State Medical Board of Ohio

30 E. Broad St., 3rd Floor
Columbus, Ohio 43215
(614) 466-3934
www.med.ohio.gov

Rules & Policies Agenda for Board Meeting
June 12, 2024

A. Rule Review Update
B. Criminal Records Check Rule
C. Physician Assistant, Anesthesiologist Assistant, and Genetic Counselor Rules
D. Dietetics Rules
E. Office-Based Opioid Treatment Rules
F. Legislative Update

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MEMORANDUM

TO: Jonathan Feibel, M.D., President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Update

DATE: June 6, 2024

Attached please find the rule spreadsheet and rule schedule for June 2024.

Requested Action: No action requested.

Legal Dept. Rules Schedule

As of June 6, 2024

Rules Filed with CSI-Comments Due 4.19.24

Office-Based Opioid Treatment Rules

Chapter 4730-4

Chapter 4731-33

Rules Proposed for Initial Circulation

Criminal Records Checks

4731-4-01

4731-4-02

Rules Proposed for Approval to File with CSI

Physician Assistant Rules

4730-1-06 4730-2-04

4731-2-05 4731-2-10

Anesthesiologist Assistant Rules

4731-24-01

4731-24-02

4731-24-03

Genetic Counselor Rules

4778-1-01 4778-1-02

4778-1-03 4778-1-05

4778-1-06

Dietetics Rules

4759-2-01 4759-5-03

4759-4-01 4759-5-04

4759-4-02 4759-5-05

4759-4-03 4759-5-06

4759-4-04 4759-6-01

4759-4-08 4759-6-02

4759-4-09 4759-6-03

4759-5-01 4759-9-01

4759-5-02

Rules Approved to File with CSI:

Notice of Meetings

4731-7-01

Recordation of Meetings

4731-9-01

Termination of Physician-Patient Relationship

4731-27-01

4731-27-02

4731-27-03

Return of Athlete to Practice of Competition

4731-31-01

Standards for Prescribing Dangerous Drugs for Administration By Injection by a Pharmacist

4731-34-01

Rules Approved for Initial Circulation:

Respiratory Care Rules (Chapter 4761)

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4730-1-01	Regulation of Physician Assistants - Definitions		06/12/19	07/16/19	11/07/19	06/18/20	No change rule			09/16/20	06/18/25	
4730-1-05	Quality Assurance System		06/12/19	07/16/19	11/07/19	06/19/20	No change rule			09/17/20	06/19/25	
4730-1-06	Licensure as a physician assistant	04/01/24									03/28/24	Extension given for Review Date
4730-1-07	Miscellaneous Provisions	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	02/28/28	
4730-2-01	Physician Delegated Prescriptive Authority - Definitions		06/12/19	07/16/19	11/07/19	06/18/20	No change rule	01/30/23	02/08/23	02/28/23	02/28/28	
4730-2-04	Period of on-site supervision of physician-delegated prescriptive authority	04/01/24									11/15/23	
4730-2-05	Addition of valid prescriber number after initial licensure	04/01/24									09/30/23	
4730-2-07	Standards for Prescribing	02/12/22	05/11/22	05/16/22	09/22/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4730-2-10	Standards and Procedures for use of OARRS	04/01/24									03/28/24	Extension given for Review Date
4730-4-01	Definitions	09/15/23	03/13/24	04/04/24							04/30/24	
4730-4-02	Standards and procedures for withdrawal management for drug or alcohol addition	09/15/23	03/13/24	04/04/24							10/31/25	
4730-4-03	Office Based Treatment for Opioid addiction	09/15/23	03/13/24	04/04/24							04/30/24	
4730-4-04	Medication assisted treatment using naltrexone	09/15/23	03/13/24	04/04/24							04/30/24	
4731-1-01	Limited Practitioners - Definition of Terms	06/17/21		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-1-02	Application of Rules Governing Limited Branches of Medicine or Surgery	06/17/21		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	07/31/24	
4731-1-03	General Prohibitions	06/17/21		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-1-04	Scope of Practice: Mechanotherapy	06/17/21		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-1-05	Scope of Practice: Massage Therapy	06/17/21		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	11/05/24	
4731-1-06	Scope of Practice: Naprapathy									08/31/18	08/31/23	
4731-1-07	*Eligibility of Electrologists Licensed by the Ohio State Board of Cosmetology to Obtain Licensure as Cosmetic Therapists Pursuant to Chapter 4731 ORC and Subsequent Limitations*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4731-1-08	*Continuing Cosmetic Therapy Education Requirements for Registration or Reinstatement of a License to Practice Cosmetic Therapy*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-09	*Cosmetic Therapy Curriculum Requirements*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-10	*Distance Education*	*06/17/21*		09/22/22	*10/31/22*	*11/29/22*	*01/04/23*	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-11	*Application and Certification for certificate to practice cosmetic therapy*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-12	*Examination*			09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*	*02/28/28*	
4731-1-15	*Determination of Standing of School, College or Institution*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-16	*Massage Therapy curriculum rule (Five year review)*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-17	*Instructional Staff*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-18	*Grounds for Suspension, Revocation or Denial of Certificate of Good Standing, Hearing Rights*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1- 19	*Probationary Status of a limited branch school*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-2-01	Public Notice of Rules Procedure	05/15/22			10/31/22	09/28/22				09/28/22	09/28/27	
4731-4-01	Criminal Records Checks - Definitions	03/04/24	04/10/24							09/30/19	09/30/24	
4731-4-02	Criminal Records Checks	03/04/24	04/10/24							09/30/19	09/30/24	
4731-5-01	*Admission to Examinations*	*05/15/22*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-5-02	*Examination Failure; Inspection and Regrading*	*05/15/22*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-5-03	*Conduct During Examinations*	*05/15/22*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-5-04	*Termination of Examinations*	*05/15/22*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-6-01	Medical or Osteopathic Licensure: Definitions				10/31/22					07/31/19	07/31/24	
4731-6-02	Preliminary Education for Medical and Osteopathic Licensure				10/31/22					07/31/19	07/31/24	
4731-6-04	Demonstration of proficiency in spoken English	05/15/22		09/22/22	10/31/22	11/14/22			no change	11/14/22	11/14/27	
4731-6-05	Format of Medical and Osteopathic Examination		09/08/21	09/24/21	10/27/21	10/29/21	12/03/21		01/12/22	01/31/22	01/31/27	
4731-6-14	Examination for physician licensure	09/03/20								07/31/19	07/31/24	
4731-6-15	Eligibility for Licensure of National Board Diplomats and Medical Council of Canada Licentiates									07/31/19	07/31/24	
4731-6-21	Application Procedures for Certificate Issuance; Investigation; Notice of Hearing Rights									07/31/19	07/31/24	

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4731-6-22	Abandonment and Withdrawal of Medical and Osteopathic Licensure Applications									07/31/19	07/31/24	
4731-6-30	Training Certificates									07/31/19	07/31/24	
4731-6-31	Limited Preexamination Registration and Limited Certification									07/31/19	07/31/24	
4731-6-33	Special Activity Certificates									07/31/19	07/31/24	
4731-6-34	Volunteer's Certificates									07/31/19	07/31/24	
4731-7-01	Method of Notice of Meetings	03/04/24	04/10/24							07/31/19	07/31/24	
4731-8-01	Personal Information Systems	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26	
4731-8-02	Definitions	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26	
4731-8-03	Procedures for accessing confidential personal information	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26	
4731-8-04	Valid reasons for accessing confidential personal information	04/29/20		10/05/20	11/18/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-8-05	Confidentiality Statutes	04/29/20		10/05/20	11/18/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-8-06	Restricting & Logging access to confidential personal information	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26	
4731-9-01	Record of Board Meetings; Recording, Filming, and Photographing of Meetings	03/04/24	04/10/24							09/15/19	06/17/24	
4731-10-01	Definitions	10/25/19		05/26/20		Revised filing 11/3/20 10/30/20	12/04/20	12/07/20	05/12/21	05/31/21	05/31/26	
4731-10-02	Requisite Hours of Continuing Medical Education for License Renewal or Reinstatement	10/25/19		05/26/20		Revised filing 11/3/20 10/30/20	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-10-03	CME Waiver	10/25/19		05/26/20		Revised filings 11/24 & 11/3 - orig 10/30/20	12/04/20	12/07/20	05/12/21	05/31/21	05/31/26	
4731-10-04	Continuing Medical Education Requirements for Restoration of a License	10/25/19		05/26/20		Revised filings 11/24 & 11/3 - orig 10/30/20	12/04/20	12/07/20	05/12/21	05/31/21	05/31/26	

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4371-10-08	Evidence of Continuing Medical Education	10/25/19		05/26/20		Revised filings 11/24 & 11/3 - orig 10/30/20	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-11-01	Controlled substances; General Provisions Definitions	02/12/22								10/31/20	10/31/25	
4731-11-02	Controlled Substances - General Provisions	07/26/19	11/13/19	10/05/20		05/27/21			no change		05/27/26	
4731-11-03	Schedule II Controlled Substance Stimulants			09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-11-04	Controlled Substances: Utilization for Weight Reduction			09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-11-04.1	Controlled substances: Utilization for chronic weight management			09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	Recinded	Rescinded
4731-11-07	Research Utilizing Controlled Substances	07/26/19	11/13/19	10/05/20		05/27/21			no change		05/27/26	
4731-11-08	Utilizing Controlled Substances for Self and Family Members	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26	
4731-11-09	Controlled Substance and telehealth prescribing	02/12/22	05/11/22	05/16/22	09/22/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-11-11	Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).	07/26/19	11/13/19	10/05/20		05/27/21	06/28/21		09/08/21	09/30/21	09/30/26	
4731-11-13	Prescribing of Opioid Analgesics for Acute Pain									08/31/17	08/31/22	
4731-11-14	Prescribing for subacute and chronic pain	11/18/22				04/17/23	05/24/23	06/01/23			12/23/23	
4731-12-01	Preliminary Education for Licensure in Podiatric Medicine and Surgery	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-12-02	Standing of Colleges of Podiatric Surgery and Medicine	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/02/23	02/28/28	
4731-12-03	Eligibility for the Examination in Podiatric Surgery and Medicine	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-12-04	Eligibility of Licensure in Podiatric Medicine and Surgery by Endorsement from Another State	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23		Rescinded
4731-12-05	Application Procedures for Licensure in Podiatric Medicine and Surgery, Investigation, Notice of Hearing Rights.	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-12-06	Visiting Podiatric Faculty Certificates	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23		Rescinded
4731-12-07	Podiatric Training Certificates	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-13-01	Conduct of Hearings - Representative; Appearances	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4731-13-02	Filing Request for Hearing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	No change				04/12/26	
4731-13-03	Authority and Duties of Hearing Examiners	08/26/20	10/14/20	amended filing 1/6/21 10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-04	Consolidation	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-05	Intervention	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-06	Continuance of Hearing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-07	Motions	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-07.1	Form and page limitations for briefs and memoranda	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-08	Filing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-09	Service	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-10	Computation and Extension of Time	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-11	Notice of Hearings	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-12	Transcripts	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-13	Subpoenas for Purposes of Hearing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-14	Mileage Reimbursement and Witness Fees	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-15	Reports and Recommendations	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-16	Reinstatement or Restoration of Certificate	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-17	Settlements, Dismissals, and Voluntary Surrenders	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-18	Exchange of Documents and Witness Lists	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-20	Depositions in Lieu of Live Testimony and Transcripts in place of Prior Testimony	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-20.1	Electronic Testimony	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-21	Prior Action by the State Medical Board	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-22	Stipulation of Facts	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-23	Witnesses	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-24	Conviction of a Crime	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	

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4731-13-25	Evidence	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-26	Broadcasting and Photographing Administrative Hearings	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-27	Sexual Misconduct Evidence	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-28	Supervision of Hearing Examiners	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-30	Prehearing Conference	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-31	Transcripts of Prior Testimony	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-32	Prior Statements of the Respondent	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-33	Physician's Desk Physician	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-34	Ex Parte Communication	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-35	Severability	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-36	Disciplinary Actions	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-14-01	Pronouncement of Death	01/25/21	03/10/21	03/18/21		05/27/21	06/28/21		09/08/21	09/30/21	09/30/26	
4731-15-01	Licensee Reporting Requirement; Exceptions	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-15-02	Healthcare Facility Reporting Requirement	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/12	11/30/23	11/30/28	
4731-15-03	Malpractice Reporting Requirement	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-15-04	Professional Society Reporting	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-15-05	Liability; Reporting Forms; Confidentially and Disclosure	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-01	Rules governing impaired physicians and approval of treatments programs - Definitions	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-02	General Procedures in Impairment Cases	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-04	Other Violations	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-05	Examinations	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-06	Consent Agreements and Orders for Reinstatement of Impaired Practitioners	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-07	Treatment Provider Program Obligations	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-08	Criteria for Approval	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-09	Procedures for Approval	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-10	Aftercare Contracts	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4731-16-11	Revocation, Suspension, or Denial of Certificate of Good Standing	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-12	Out-of-State Impairment Cases	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-13	Patient Consent; Revocation of Consent	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-14	Caffeine, Nicotine, and Over-The Counter Drugs	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-15	Patient Rights	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-17	Requirements for the one-bite program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-18	Eligibility for the one-bite program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-19	Monitoring organization for one-bite program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-20	Treatment providers in the one-bite program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-21	Continuing care for the one-bite program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/24	Rescinded	
4731-17-01	Exposure-Prone Invasive Procedure Precautions - Definitions	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-17-02	Universal Precautions	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21			no change		02/11/26	
4731-17-03	Hand Washing	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21			no change		02/11/26	
4731-17-04	Disinfection and Sterilization	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-17-05	Handling and Disposal of Sharps and Wastes	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-17-06	Barrier Techniques	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21			no change		02/11/26	
4731-17-07	Violations	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-18-01	Definitions			09/22/22	12/22/22	03/06/23	02/10/23	03/06/23	04/12/23	04/30/23	04/30/28	
4731-18-02	Use of Light Based Medical Devices			09/22/22	12/22/22	03/06/23	02/10/23	03/06/23	04/12/23	04/30/23	04/30/28	
4731-18-03	Delegation of the Use of Light Based Medical Devices			09/22/22	12/22/22	03/06/23	02/10/23	03/06/23	04/12/23	04/30/23	04/30/28	
4731-18-04	Delegation of phototherapy and photodynamic therapy	01/10/18	01/20/20	05/12/20	04/05/21	04/09/21	refiled 6-9-21 5/17/2021	06/25/21	07/14/21	07/31/21	07/31/26	
4731-20-01	Surgery Privileges of Podiatrist - Definition of Foot	10/16/23	11/08/23	11/09/23		01/23/24		04/15/24			01/23/29	
4731-20-02	Surgery: Ankle Joint	10/16/23	11/08/23	11/09/23		01/23/24		04/15/24			01/23/29	
4731-22-01	Retired License Status	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	02/29/24	02/28/29	
4731-22-02	Application	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		
4731-22-03	Status of Registrant	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4731-22-04	Continuing Education Requirements	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		
4731-22-06	Renewal of Cycle of Fees	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		
4731-22-07	Change to Active Status	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		
4731-22-08	Cancellation of or Refusal to Issue an Emeritus Registration	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		
4731-23-01	Delegation of Medical Tasks - Definitions	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26	
4731-23-02	Delegation of Medical Tasks	01/25/21	03/10/21	03/18/21	04/23/21	refiled 7/14/21 5/27/2021	06/28/21		09/08/21	09/30/21	09/30/26	
4731-23-03	Delegation of Medical Tasks: Prohibitions	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26	
4731-23-04	Violations	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26	
4731-24-01	Anesthesiologist Assistants - Definitions	04/01/24									07/31/24	
4731-24-02	Anesthesiologist Assistants; Supervision	04/01/24									07/31/24	
4731-24-03	Anesthesiologist Assistants; Enhanced Supervision	04/01/24									07/31/24	
4731-25-01	Office-Based Surgery - Definition of Terms	06/16/23									03/01/23	
4731-25-02	General Provisions	06/16/23	01/10/24	01/19/24	02/15/24	02/16/24	03/27/24	04/15/24		05/18/24	05/18/29	
4731-25-03	Standards for Surgery Using Moderate Sedation/Analgesia	06/16/23								05/31/18	08/31/23	
4731-25-04	Standards for Surgery Using Anesthesia Services	06/16/23								05/31/18	05/31/23	
4731-25-05	Liposuction in the Office Setting	06/16/23								03/01/18	03/01/23	
4731-25-07	Accreditation of Office Settings	06/16/23								05/31/18	05/31/23	
4731-25-08	Standards for Surgery	06/16/23								09/30/19	09/30/24	
4731-26-01	Sexual Misconduct - Definitions	01/25/21	03/10/21	03/18/21	04/23/21	refiled 7/14/21 5/27/2021	06/28/21		09/08/21	09/30/21	09/30/26	
4731-26-02	Prohibitions	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21	06/28/21		09/08/21	09/30/21	09/30/26	
4731-26-03	Violations; Miscellaneous	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21	06/28/21		09/08/21	09/30/21	09/30/26	
4731-27-01	Definitions	03/04/24								02/04/19	02/02/24	
4731-27-02	Dismissing a patient from the medical practice	03/04/24								05/31/19	05/31/24	
4731-27-03	Notice of termination of physician employment or physician leaving a practice, selling a practice, or retiring from the practice of medicine	03/04/24								05/31/19	05/31/24	see comments for future folder

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4731-28-01	Mental or Physical Impairment	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-28-02	Eligibility for confidential monitoring program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-28-03	Participation in the confidential monitoring program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-28-04	Disqualification from continued participation in the confidential monitoring program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-28-05	Termination of the participation agreement for the confidential monitoring program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-29-01	Standards and procedures for operation of a pain management clinic.									06/30/17	06/30/22	
4731-30-01	Internal Management Definitions									09/23/18	09/23/23	
4731-30-02	Internal Management Board Metrics	07/26/19								09/23/18	09/23/23	
4731-30-03	Approval of Licensure Applications	08/28/23							10/11/23	10/31/23	10/17/24	
4731-30-04	Maintenance of List of Disqualifying Criminal Offenses	08/13/21				refiled 11-4-21			09/08/21	12/31/21	12/31/26	
4731-31-01	Requirements for assessing and granting clearance for return to practice or competition. (concussion rule)	03/04/24	04/10/24							11/30/19	11/30/24	
4731-32-01	Definition of Terms	02/09/23	03/08/23	03/30/23	08/31/23	11/28/23	01/04/24	01/08/24	02/14/24	02/29/24	02/28/29	
4731-32-02	Certificate to Recommend Medical Marijuana	02/09/23	03/08/23	03/30/23	08/31/23	11/28/23	01/04/24	01/08/24	02/14/24	02/29/24	02/28/29	
4731-32-03	Standard of Care	02/09/23	03/08/23	03/30/23	08/31/23	11/28/23	01/04/24	01/08/24	02/14/24	02/29/24	02/28/29	
4731-32-04	Suspension and Revocation of Certificate to Recommend	02/09/23	03/08/23	03/30/23	08/31/23	11/28/23	No change rule	01/08/24	N/A	02/27/24	11/28/28	
4731-32-05	Petition to Request Additional Qualifying Condtion or Disease	02/09/23	03/08/23	03/30/23	08/31/23	11/28/23	No change rule	01/08/24	N/A	02/27/24	11/28/28	
4731-33-01	Definitions	09/15/23	03/13/24	04/04/24							04/30/24	
4731-33-02	Standards and procedures for withdrawal managment for drug or alcohol addiction	09/15/23	03/13/24	04/04/24							10/31/25	
4731-33-03	Office-Based Treatment for Opioid Addiction	09/15/23	03/13/24	04/04/24							04/30/24	
4731-33-04	Medication Assisted Treatment Using Naltrexone	09/15/23	03/13/24	04/04/24							04/30/24	

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4731-34-01	Standards and Procedures to be followed by physicians when prescribing a dangerous drug that may be administered by a pharmacist by injection.	03/04/24	04/10/24							07/31/19	07/31/24	
4731-35-01	Consult Agreements	01/25/21	04/14/21	04/26/21	06/04/21	09/22/21	10/29/21	11/08/21	12/08/21	12/31/21	10/31/25	
4731-35-02	Standards for managing drug therapy	01/25/21	04/14/21	04/26/21	06/04/21	09/22/21	10/29/21	11/08/21	12/08/21	12/31/21	10/31/25	
4731-36-01	Military provisions related to education and experience requirements for licensure	06/17/21	09/08/21	09/24/21	10/27/21	10/29/21	12/03/21		01/12/22	01/31/22	10/29/21	and 1/31/27
4731-36-02	Military provisions related to renewal of license and continuing education	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25	
4731-36-03	Processing applications from service members, veterans, or spouses of service members or veterans.	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25	
4731-36-04	Temporary license for military spouse	02/11/20	02/12/20	02/14/20		02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-37-01	Telehealth	02/12/22	05/11/22	05/16/22	09/22/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-38-01	Licenses Issued or Renewed Under the Interstate Medical Licensure Compact	11/12/21	01/12/22	01/14/22	02/14/22	02/18/22	03/25/22		05/11/22	05/31/22	05/31/27	
4731-38-02	Issuance of Licenses to Out-of-State Licensees or Certificate Holders	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4759-2-01	Definitions	03/04/24								11/30/19	11/30/24	
4759-4-01	Applications	03/04/24								11/30/19	11/30/24	
4759-4-02	Preprofessional experience	03/04/24									08/28/24	
4759-4-03	Examination	03/04/24								11/30/19	11/30/24	
4759-4-04	Continuing Education	03/04/24								07/31/21	07/31/26	
4759-4-08	Limited permit	03/04/24								07/31/21	07/31/26	
4759-4-09	License certificates and permits	03/04/24								11/30/19	11/30/24	
4759-5-01	Supervision of persons claiming exemption	03/04/24								08/28/19	08/28/24	
4759-5-02	Student practice exemption	03/04/24								11/30/19	11/30/24	
4759-5-03	Plan of treatment exemption	03/04/24								11/30/19	11/30/24	
4759-5-04	Additional nutritional activities exemption	03/04/24									07/01/24	
4759-5-05	Distribution of literature exemption	03/04/24									07/01/24	
4759-5-06	Weight control program exemption	03/04/24									07/01/24	
4759-6-01	Standards of practice innutrition care	03/04/24								11/30/19	11/30/24	
4759-6-02	Standards of professional performance	03/04/24								07/31/21	07/31/26	
4759-6-03	Interpretation of standards	03/04/24								11/30/19	11/30/24	
4759-9-01	Severability	03/04/24								11/30/19	11/30/24	
4759-11-01	Miscellaneous Provisions	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	*11/08/23*	11/30/23	11/30/28	
4761-2-03	Board Records									02/28/19	02/28/24	
4761-3-01	Definition of terms									02/28/19	02/28/24	
4761-4-01	Approval of educational programs									02/28/19	02/28/24	

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4761-4-02	Monitoring of Ohio respiratory care educational programs									02/28/19	02/28/24	
4761-5-01	Waiver of licensing requirements pursuant to division (B) of section 4761.04 or the Revised Code	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25	
4761-5-02	Admission to the Ohio credentialing examination	04/23/19	06/12/19	11/06/19	01/10/20	06/19/20	No change rule			09/19/20	06/19/25	
4761-5-04	License application procedure	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25	
4761-5-06	Respiratory care practice by polysomnographic technologists	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	No change rule			09/18/20	06/18/25	
4761-6-01	Limited permit application procedure	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	02/28/24	
4761-7-01	Original license or permit, identification card or electronic license verification									02/28/19	02/28/24	
4761-7-03	Scope of respiratory care defined										11/15/23	
4761-7-04	Supervision			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25	
4761-7-05	Administration of medicines										11/15/23	
4761-8-01	Renewal of license or permits	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25	
4761-9-01	Defnition of respiratory care continuing education			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	02/28/24	
4761-9-02	General RCCE requirements and reporting mechanism	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25	
4761-9-03	Activities which do not meet the Ohio RCCE requirements									02/28/19	02/28/24	
4761-9-04	Ohio respiratory care law and professional ethics course criteria			11/06/19	01/10/20	Refiled 8/24/20 6/18/2020	9/24/20 7/23/2020	08/17/20	11/10/20		02/28/24	Look at adding OOA as an approving organization
4761-9-05	Approved sources of RCCE			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	02/28/24	Look at adding OOA as an approving organization
4761-9-07	Auditing for compliance with RCCE requirements			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25	
4761-10-01	Ethical and professional conduct									02/28/19	02/28/24	
4761-10-02	Proper use of credentials										11/15/23	
4761-10-03	Providing information to the Board	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25	
4761-15-01	Miscellaneous Provisions	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4774-1-01	Definitions	04/29/20	10/14/20	10/23/20	11/24/20	02/11/21			no change	02/11/21	02/11/26	
4774-1-02	Application for Certificate to Practice	04/29/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4774-1-03	Renewal of Certificate to Practice	04/29/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4774-1-04	Miscellaneous Provisions	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4778-1-01	Definition	04/01/24									01/24/24	

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4778-1-02	Application	04/01/24									04/30/24	
4778-1-03	Special Activity License	04/01/24									01/24/24	
4778-1-05	Collaboration Agreement	04/01/24									04/30/24	
4778-1-06	Miscellaneous Provisions	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	

State Medical Board of Ohio

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MEMORANDUM

TO: Jonathan Feibel, M.D., President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Criminal Records Check Rules

DATE: June 5, 2024

The rules related to criminal records checks for license applicants are due for five year review. A few edits are needed to address the new process for reactivating a license in retired license status, granting of a reciprocal license, and for the disqualifying offense list process.

The rules, as amended, are attached for your review:

4731-4-01	Definitions	Proposed to Amend
4731-4-02	Criminal Records Checks	Proposed to Amend

Requested Action: Circulate rules to stakeholders for comment.

4731-4-01 **Definitions.**

(A) "Applicant for an initial license or certificate to practice" includes a person seeking an initial license or certificate to practice under Chapter 4730., 4731., 4759., 4760. , 4761., 4762., 4774., ~~or~~ 4778., or 4796. of the Revised Code.

(B) "Applicant for a restored license or certificate to practice" includes a person seeking restoration of a license or certificate to practice pursuant to Chapter 4730., 4731., 4759., 4760., 4761., 4762., 4774., or 4778. of the Revised Code.

(C) "Applicant for a reactivated license or certificate to practice" includes a person seeking to reactivate a retired license or certificate to practice pursuant to Chapter 4730., 4731., 4759., 4760., 4761., 4762., 4774., or 4778. of the Revised Code.

(D) ~~(C)~~ "Criminal records check" has the same meaning as in division (G) of section 109.572 of the Revised Code.

(E) ~~(D)~~ BCI means the "Ohio Bureau of Criminal Identification and Investigation."

(F) ~~(E)~~ "FBI" means the "Federal Bureau of Investigation."

4731-4-02 **Criminal records checks.**

(A) An applicant for an initial license or certificate to practice, for a reactivated license or certificate to practice, or for a restored license or certificate to practice pursuant to Chapter 4730., 4731., 4759., 4760, 4761., 4762., 4774., ~~or~~ 4778., or 4796. of the Revised Code, shall submit fingerprints, required forms, and required fees to BCI for completion of BCI and FBI criminal records checks.

(1) An applicant who is present in Ohio shall use the services of an entity that has been designated by the Ohio attorney general to participate in the "National WebCheck" program (available at http://www.ohioattorneygeneral.gov/) and pay any processing fee charged by the entity, with the "State Medical Board of Ohio" designated to receive the results:

(2) An applicant who resides in a state or jurisdiction other than Ohio shall either appear in Ohio in order to comply with the requirements of paragraph (A)(1) of this rule or request that the board provide the forms required to complete the criminal records checks.

Upon receipt of the forms, the applicant shall have his or her fingerprints processed and pay any applicable processing fees.

(B) The board shall maintain the criminal records check reports in a manner that ensures the confidentiality of the results, prevents disclosure pursuant to a public records request, and complies with applicable state and federal requirements.

(C) The board shall not accept the results of a criminal records check submitted by an entity other than BCI.

(D) In reviewing the results of criminal records checks to determine whether the applicant should be granted ~~an initial~~ a reactivated or restored license or certificate to practice, the board may consider all of the following:

(1) The nature and seriousness of the crime;

(2) The extent of the applicant's past criminal activity;

(3) The age of the applicant when the crime was committed;

(4) The amount of time that has elapsed since the applicant's last criminal activity;

(5) The conduct and work activity of the applicant before and after the criminal activity;

(6) Whether the applicant has completed the terms of any probation or deferred adjudication;

(7) Evidence of the applicant's rehabilitation;

(8) Whether the applicant fully disclosed the arrest or conviction to the board; and

(9) Any other factors the board considers relevant.

(E) In reviewing the results of criminal records checks to determine whether an applicant should be granted an initial license or certificate to practice, the board shall comply with section 9.79 of the Revised Code.

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MEMORANDUM

TO: Jonathan Feibel, M.D., President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rules for Five-Year Review for Physician Assistants, Anesthesiologist Assistants, and Genetic Counselors

DATE: June 4, 2024

The attached rules were circulated to interested parties with comments due April 19, 2024. No comments were received.

Physician Assistant

4730-1-06	Licensure as a Physician Assistant-Proposed No Change
4730-2-04	Period of On-Site Supervision of Physician-Delegated Prescriptive Authority-Proposed No Change
4730-2-05	Addition of Valid Prescriber Number After Initial Licensure-Proposed No Change
4730-2-10	Standards and Procedures for Review of "Ohio Automated RX Reporting System ("OARRS")-Proposed No Change

Anesthesiologist Assistant

4731-24-01	Definitions-Proposed No Change
4731-24-02	Anesthesiologist Assistants: Supervision-Proposed No Change
4731-24-03	Anesthesiologist Assistants: Enhanced Supervision-Proposed No Change

Genetic Counselors

4778-1-01	Definitions-Proposed No Change
4778-1-02	Application for a License-Proposed to Amend
4778-1-03	Special Activity License-Proposed No Change
4778-1-05	Collaboration Agreement-Proposed No Change

Requested Action: Approve proposed rules for filing with the Common Sense Initiative.

4730-1-06 **Licensure as a physician assistant.**

(A) All applicants for a physician assistant license shall submit an application under oath in the manner prescribed by the board and provide such other facts and materials as the board requires.

(B) No application shall be considered filed, and shall not be reviewed, until the fee required by section 4730.10 of the Revised Code has been received by the board.

(C) An application shall be considered complete when all of the following requirements are met:

(1) The fee required pursuant to section 4730.10 of the Revised Code has been received by the board;

(2) Verification of the applicant's current certification has been received by the board directly from the "National Commission on Certification of Physician Assistants";

(3) All information required by section 4730.10 of the Revised Code, including such other facts and materials as the board requires, has been received by the board; and

(4) The applicant has complied with the requirements of paragraph (A) of rule 4731-4-02 of the Administrative Code and the board has received the results of the criminal records checks.

(5) The board is not conducting an investigation, pursuant to section 4730.26 of the Revised Code, of evidence appearing to show that the applicant has violated section 4730.25 of the Revised Code or applicable rules adopted by the board.

(D) All application materials submitted to the board will be thoroughly investigated. The board will contact individuals, agencies, or organizations for information about applicants as the board deems necessary. As part of the application process, an applicant may be requested to appear before the board or a representative thereof to answer questions or provide additional information.

(E) Applications received from service members, veterans, or spouses of service members or veterans shall be identified and processed in accordance with rule 4731-36-03 of the Administrative Code.

(F) The following processes apply when an application is not complete within six months of the date the application is filed with the board:

(1) If an applicant fails to complete the application process within six months of initial application filing, the board may notify the applicant in writing of its intention to consider the application abandoned. If no response to that notice is received by the board within thirty days, the board shall consider the application as abandoned and no further processing shall be undertaken with respect to that application.

(2) If the application is not complete because the board is investigating, pursuant to section 4730.26 of the Revised Code, evidence appearing to show that the applicant has violated Chapter 4730. of the Revised Code or applicable rules adopted by the board, the board shall do both of the following:

(a) Notify the applicant that although otherwise complete, the application will not be processed pending completion of the investigation; and

(b) Upon completion of the investigation and the determination that the applicant is not in violation of statute or rule, process the application, including requiring updated information as it deems necessary.

(G) A physician assistant license must be renewed in the manner and according to the requirements of section 4730.14 of the Revised Code.

(H) To qualify for renewal of a physician assistant license, the holder shall comply with the following:

(1) Each applicant for renewal shall certify that the applicant has completed the requisite hours of CME since the start of the licensure registration period.

(2) Except as provided in paragraph (I)(4) of this rule, a physician assistant shall have completed one hundred hours of CME during the licensure registration period.

(3) Pursuant to the provisions of section 4745.04 of the Revised Code, the board shall permit a physician assistant to earn one hour of CME for each sixty minutes spent providing health care services in Ohio, as a volunteer, to indigent and unisured persons, up to a maximum of thirty-three hours per CME period. Physician assistants seeking to receive credit toward CME requirements shall maintain a log of their qualifying activities. The log shall indicate the dates the health care services were provided, the number of hours spent providing health care services on those dates, the location where the health care services were provided, and the signature of the medical director or the medical director's designee.

(4) Proration of hours required:

(a) If the physician assistant license is initially issued prior to the first day of the second year of a licensure period, the licensee shall be required to earn fifty total hours; if the license is issued on or after the first day of the second year of the licensure period and prior to the first day of the eighteenth month of that licensure period, the licensee shall be required to earn twenty-five total hours; if the license is issued on or after the first day of the eighteenth month of a licensure period, the licensee shall not be required to earn any hours of CME for that licensure period.

(b) Pursuant to the provisions of section 4745.04 of the Revised Code, the board shall permit a physician assistant to earn one hour of CME for each sixty minutes spent providing health care services in Ohio, as a volunteer, to indigent and uninsured persons, when it is documented as required by paragraph (I)(3) of this rule, up to the following maximums:

(i) For a physician assistant required to earn fifty total hours, a maximum of sixteen hours for that CME period.

(ii) For a physician assistant required to earn twenty-five total hours, a maximum of eight hours for that CME period.

(5) Only those hours earned from the date of licensure to the end of the licensure period shall be used towards the total hour requirement as contained in this rule.

(6) Completion of the CME requirement may be satisfied by courses acceptable for the individual to maintain NCCPA certification.

(I) To qualify for renewal of a physician assistant license with a valid prescriber number, the physician assistant shall comply with all of the following requirements:

(1) Completion of the requirements in paragraph (H) of the rule;

(2) Except as provided in paragraph (I)(4) of this rule, completion of at least twelve hours of category I continuing education in pharmacology.

(3) If the physician assistant prescribes opioid analgesics or benzodiazepines, the applicant for renewal shall certify having been granted access to OARRS,

unless one of the exemptions in section 4730.49 of the Revised Code is applicable.

(4) If the renewal of the license with a valid prescriber number is the first renewal after the holder has completed the five hundred hours of on site supervision required by section 4730.44 of the Revised Code, the requisite hours of pharmacology continuing education are as follows:

(a) If the five hundred hours were completed prior to the first day of the second year of the licensure period, the licensee shall be required to earn six total hours of pharmacology continuing education;

(b) If the five hundred hours were completed on or after the first day of the second year of the licensure period and prior to the eighteenth month of that licensure period, the licensee shall be required to earn three total hours;

(c) If the five hundred hours were completed on or after the first day of the eighteenth month of a licensure period, the licensee shall not be required to earn any hours of pharmacology continuing education for that licensure period.

4730-2-04 **Period of on-site supervision of physician-delegated prescriptive authority.**

(A) The following definitions are applicable to this rule:

(1) "Supervision" means the supervising physician maintains oversight of the physician assistant's prescriptive decisions and provides timely review of prescriptions written by the physician assistant.

(2) "On-site supervision" means the supervising physician is required to be physically present within the facility where the physician assistant is practicing and available for consultation. The supervising physician is not necessarily required to personally evaluate a patient to whom a physician assistant is providing service.

(3) "Supervising physician" includes a primary supervising physician in instances where the physician assistant has supervision agreements with multiple supervising physicians and one supervising physician is designated to have primary responsibility for the supervision of the physician assistant's prescribing activities during the on-site supervision period.

(B) Except as provided in division (B) of section 4730.44 of the Revised Code, the first five hundred hours of a physician assistant's exercise of physician-delegated prescriptive authority shall be under the on-site supervision of a supervising physician with whom the physician assistant has a supervision agreement.

(1) The supervising physician shall review and evaluate the physician assistant's competence, knowledge, and skill in pharmacokinetic principles and the application of these principles to the physician assistant's area of practice. The supervising physician shall document the review and evaluation by signing patient charts in a legible manner or documenting the review and evaluation by the use of an electronically generated signature provided that reasonable measures have been taken to prevent the unauthorized use of the electronically generated signature.

(2) The supervising physician shall maintain a record evidencing that the physician assistant has completed at least five hundred hours of on-site supervision and make the record available to the board upon request.

(C) On-site supervision period hours completed may be transferred to an on-site supervision period under a subsequent supervising physician pursuant to the following criteria:

(1) Hours completed may be transferred, not more than one time, when both of the following criteria are met:

(a) The initial supervising physician provides written verification of the activities and number of hours successfully completed by the physician assistant during the period; and

(b) The subsequent supervising physician approves the transfer of the period hours.

(2) Hours completed under the supervision of the subsequent supervising physician may be transferred to an on-site supervision period under a third supervising physician only upon the board's approval when all of the following conditions are met:

(a) The subsequent supervising physician provides both of the following:

(i) Written verification of the activities and number of hours successfully completed during the period to date; and

(ii) Written explanation of why the transfer of hours is being requested;

(b) The third supervising physician approves the transfer of the hours;

(c) The failure to transfer the hours would result in undue hardship to the physician assistant; and

(d) The granting of the transfer would not jeopardize patient care.

(D) Where the exemption of division (B) of section 4730.44 of the Revised Code is claimed, the supervising physician shall maintain documentation establishing that the physician assistant practiced with prescriptive authority in the other jurisdiction for not less than one thousand hours. The documentation may include a letter from one or more physicians who supervised the physician assistant's prescribing in that jurisdiction verifying that the physician assistant practiced with prescriptive authority in that jurisdiction for not less than one thousand hours or a letter from an appropriate facility administrator verifying that the physician assistant practiced with prescriptive authority for not less than one thousand hours based upon documentation in the physician assistant's personnel file.

4730-2-05 **Addition of valid prescriber number after initial licensure.**

(A) All applicants for a prescriber number subsequent to initial licensure shall submit an endorsement application in the manner determined by the board.

(B) An endorsement application shall be considered complete when all of the following requirements are met:

(1) The records of the board establish that the applicant holds a current, valid license to practice as a physician assistant in Ohio;

(2) All information required by section 4730.15 of the Revised Code, including evidence of meeting the educational requirements or practice requirements, as applicable, has been received by the board;

4730-2-10 **Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).**

(A) For purposes of this rule:

(1) "Delegate" means an authorized representative who is registered with the Ohio board of pharmacy to obtain an OARRS report on behalf of the physician assistant.

(2) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(3) "OARRS" report" means a report of information related to a specified patient generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(4) "Reported drugs" means all the drugs listed in rule 4729:8-2-01 of the Administrative Code that are required to be reported to the drug database established and maintained pursuant to section 4729.75 of the Revised Code, including controlled substances in schedules II, III, IV, and V.

(B) Standards of care:

(1) The accepted and prevailing minimal standards of care require that when prescribing a reported drug, a physician assistant shall take into account all of the following:

(a) The potential for abuse of the reported drug;

(b) The possibility that use of the reported drug may lead to dependence;

(c) The possibility the patient will obtain the reported drug for a nontherapeutic use or distribute it to other persons; and

(d) The potential existence of an illicit market for the reported drug.

(2) In considering whether a prescription for a reported drug is appropriate for the patient, the physician assistant shall use sound clinical judgment and obtain and review an OARRS report consistent with the provisions of this rule.

(C) A physician assistant shall obtain and review an OARRS report to help determine if it is appropriate to prescribe an opioid analgesic, benzodiazepine, or other reported

drug to a patient as provided in this paragraph and paragraph (F) of this rule:

(1) A physician assistant shall obtain and review an OARRS report before prescribing an opioid analgesic or benzodiazepine to a patient, unless an exception listed in paragraph (H) of this rule is applicable.

(2) A physician assistant shall obtain and review an OARRS report when a patient's course of treatment with a reported drug other than an opioid analgesic or benzodiazepine has lasted more than ninety days, unless an exception listed in paragraph (H) of this rule is applicable.

(3) A physician assistant shall obtain and review and OARRS report when any of the following red flags pertain to the patient:

(a) Selling prescription drugs;

(b) Forging or altering a prescription;

(c) Stealing or borrowing reported drugs;

(d) Increasing the dosage of reported drugs in amounts that exceed the prescribed amount;

(e) Suffering an overdose, intentional or unintentional;

(f) Having a drug screen result that is inconsistent with the treatment plan or refusing to participate in a drug screen;

(g) Having been arrested, convicted, or received diversion or intervention in lieu of conviction for a drug related offense while under the care of the physician assistant or the physician assistant's supervising physician;

(h) Receiving reported drugs from multiple prescribers, without clinical basis;

(i) Traveling with a group of other patients to the physician assistant's office where all or most of the patients request controlled substance prescriptions;

(j) Traveling an extended distance or from out of state to the physician assistant's office;

(k) Having a family member, friend, law enforcement officer, or health care professional express concern related to the patient's use of illegal or reported drugs;

(l) A known history of chemical abuse or dependency;

(m) Appearing impaired or overly sedated during an office visit or exam;

(n) Requesting reported drugs by street name, color, or identifying marks;

(o) Frequently requesting early refills of reported drugs;

(p) Frequently losing prescriptions for reported drugs;

(q) A history of illegal drug use;

(r) Sharing reported drugs with another person; or

(s) Recurring visits to non-coordinated sites of care, such as emergency departments, urgent care facilities, or walk-in clinics to obtain reported drugs.

(D) A physician assistant who decides to utilize an opioid analgesic, benzodiazepine, or other reported drug in any of the circumstances within paragraphs (C)(2) and (C)(3) of this rule shall take the following steps prior to issuing a prescription for the opioid analgesic, benzodiazepine, or other reported drug:

(1) Review and document in the patient record the reasons why the physician assistant believes or has reason to believe that the patient may be abusing or diverting drugs;

(2) Review and document in the patient's record the patient's progress toward treatment objectives over the course of treatment;

(3) Review and document in the patient record the functional status of the patient, including activities for daily living, adverse effects, analgesia, and aberrant behavior over the course of treatment;

(4) Consider using a patient treatment agreement including more frequent and periodic reviews of OARRS reports and that may also include more frequent

office visits, different treatment options, drug screens, use of one pharmacy, use of one provider for the prescription of reported drugs, and consequences for non-compliance with the terms of the agreement. The patient treatment agreement shall be maintained as part of the patient record; and

(5) Consider consulting with or referring the patient to a substance abuse specialist.

(E) Frequency for follow-up OARRS reports:

(1) For a patient whose treatment with an opioid analgesic or benzodiazepine lasts more than ninety days, a physician assistant shall obtain and review an OARRS report for the patient at least every ninety days during the course of treatment, unless an exception listed in paragraph (G) of this rule is applicable.

(2) For a patient who is treated with a reported drug other than an opioid analgesic or benzodiazepine for a period lasting more than ninety days, the physician assistant shall obtain and review an OARRS report for the patient at least annually following the initial OARRS report obtained and reviewed pursuant to paragraph (C)(2) of this rule until the course of treatment utilizing the reported drug has ended, unless an exception in paragraph (H) of this rule is applicable.

(F) When a physician assistant or their delegate requests an OARRS report in compliance with this rule, a physician assistant shall document receipt and review of the OARRS report in the patient record, as follows:

(1) Initial reports requested shall cover at least the twelve months immediately preceding the date of the request;

(2) Subsequent reports requested shall, at a minimum, cover the period from the date of the last report to present;

(3) If the physician assistant practices primarily in a county of this state that adjoins another state, the physician assistant or their delegate shall also request a report of any information available in the drug database that pertains to prescriptions issued or drugs furnished to the patient in the state adjoining that county; and

(4) If an OARRS report regarding the patient is not available, the physician assistant shall document in the patient's record the reason that the report is not

available and any efforts made in follow-up to obtain the requested information.

(G) Review of the physician assistant's compliance with this rule shall be included as an activity in the quality assurance plan required by division (F) of section 4730.21 of the Revised Code and rule 4730-1-05 of the Administrative Code.

(H) A physician assistant shall not be required to review and assess an OARRS report when prescribing an opioid analgesic, benzodiazepine, or other reported drug under the following circumstances, unless a physician assistant believes or has reason to believe that a patient may be abusing or diverting reported drugs:

(1) The reported drug is prescribed to a hospice patient in a hospice care program as those terms are defined in section 3712.01 of the Revised Code, or any other patient diagnosed as terminally ill;

(2) The reported drug is prescribed for administration in a hospital, nursing home, or residential care facility;

(3) The reported drug is prescribed in an amount indicated for a period not to exceed seven days;

(4) The reported drug is prescribed for the treatment of cancer or another condition associated with cancer.

4731-24-01 **Definitions.**

As used in Chapter 4731-24 of the Administrative Code:

(A) "Administer" means to apply directly a drug, whether by injection, inhalation, ingestion, or any other means, and the infusion of blood, blood products and supportive fluids.

(B) "Assist" means to carry out procedures as requested by the supervising anesthesiologist, provided that the requested procedure is within the anesthesiologist assistant's training and scope of practice, is authorized by the practice protocol adopted by the supervising anesthesiologist, and is not prohibited by Chapter 4731. or 4760. of the Revised Code, or by any provision of agency 4731 of the Administrative Code.

(C) "Drug" has the same meaning as in division (E) of section 4729.01 of the Revised Code.

(D) "Direct supervision, and in the immediate presence of" means the following:

(1) The supervising anesthesiologist shall remain physically present and available for immediate diagnosis and treatment of emergencies;

(2) The supervising anesthesiologist shall be physically present in the anesthetizing area or operating suite, as defined by the hospital or ambulatory surgical facility, and accessible by page, telephone, or overhead page, such that he or she is immediately available to participate directly in the care of the patient with whom the anesthesiologist assistant and the supervising anesthesiologist are jointly involved;

(3) The supervising anesthesiologist shall personally participate in the most demanding procedures in the anesthesia plan, which shall include induction and emergence; and

(4) "Direct supervision and the in immediate presence of" shall not be interpretted to:

(a) Require the supervising anesthesiologist's presence in the same room as the anesthesiologist assistant for the duration of the anesthetic management; or

(b) Prohibit the supervising anesthesiologist from addressing an emergency of short duration, administering labor analgesia, or performing duties of

short duration as required of a perioperative specialist in another location in the hospital or ambulatory surgical facilty.

4731-24-02 **Anesthesiologist assistants: supervision.**

(A) A supervising anesthesiologist shall supervise an anesthesiologist assistant within the terms, conditions, and limitations set forth in a written practice protocol that is consistent with section 4760.08 of the Revised Code and this chapter of the Administrative Code. The supervision shall be direct supervision and in the immediate presence of the anesthesiologist assistant, as that term is defined in rule 4731-24-01 of the Administrative Code.

(B) An anesthesiologist assistant shall only perform those tasks assigned on a case-by-case basis by the supervising anesthesiologist. The anesthesiologist assistant shall implement the personalized plan for a patient as individually prescribed by the supervising anesthesiologist after the physician has completed a specific assessment of the patient.

(C) In determining which anesthetic procedures to assign to an anesthesiologist assistant, a supervising anesthesiologist shall consider all of the following:

(1) The education, training, and experience of the anesthesiologist assistant;

(2) The anesthesiologist assistant's scope of practice as defined in section 4760.09 of the Revised Code and this chapter of the Administrative Code;

(3) The conditions on the practice of the anesthesiologist assistant set out in the written practice protocol;

(4) The physical status of the patient according to the physical status classification system of the American society of anesthesiologists, as in effect at the time the assignment of procedures is made. The classification system is available from the American society of anesthesiologists and shall be posted on the board's website at med.ohio.gov.

(5) The invasiveness of the anesthetic procedure;

(6) The level of risk of the anesthetic procedure;

(7) The incidence of complications of the anesthetic procedure;

(8) The physical proximity of the supervising anesthesiologist and the anesthologist assistant or assistants being supervised concurrently; and

(9) The number of patients whose care is being supervised concurrently by the

supervising anesthesiologist.

(D) During the first four years of an anesthesiologist assistant's practice, the supervising anesthesiologist shall provide enhanced supervision as defined in this chapter of the Administrative Code.

(E) The supervising anesthesiologist shall retain responsibility for the anesthetic management in which the anesthesiologist assistant has participated.

4731-24-03 **Anesthesiologist assistants: enhanced supervision.**

(A) A supervising anesthesiologist shall provide enhanced supervision of an anesthesiologist assistant during the first four years of the anesthesiologist assistant's practice.

(B) "Enhanced supervision" means the following:

(1) The supervising anesthesiologist shall require regular, documented quality assurance interactions between the supervising anesthesiologist and the anesthesiologist assistant .

(a) The regularly scheduled quality assurance interactions shall occur in greater number and with greater frequency during the first four years of an anesthesiologist assistant's practice than would be required for quality assurance purposes for anesthesiologist assistants in practice for more than four years and shall take place no less frequently than once every three months.

(b) The anesthesiologist assistant shall be required to file on a monthly basis during the first two years of practice a separate record of the cases of anesthetic management in which he or she participated. The record shall be reviewed by a supervising anesthesiologist as a component of the quality assurance interactions.

(c) The reviewing supervising anesthesiologist shall file a report of each quality assurance interaction with the appropriate committee.

(2) The supervising anesthesiologist shall make direct observations of the anesthesiologist assistant during the course of each case of anesthetic management.

(a) During the first year of an anesthesiologist assistant's practice, the direct observations of each case of anesthetic management shall be made more frequently than for comparable procedures for anesthesiologist assistants practicing beyond their first year, and include direct observation of induction and emergence.

(b) The supervising anesthesiologist shall document the enhanced supervision in the anesthetic record.

(3) The period of enhanced supervision for an anesthesiologist assistant who has practiced in another state prior to beginning practice in Ohio shall be

determined as follows:

(a) The anesthesiologist assistant shall be given credit for the time practiced in another state.

(b) The credit shall be on a year-for-year basis, except that the supervising anesthesiologist shall provide enhanced supervision as defined in this rule for the first three months of the anesthesiologist assistant's practice in Ohio.

4778-1-01 **Definitions.**

For purposes of Chapter 4778. of the Revised Code and the rules promulgated thereunder, the following definitions apply:

(A) “Board” means the state medical board of Ohio.

(B) “Rare disease” means any disease affecting approximately one in one thousand five hundred people.

4778-1-02 **Application for a license.**

(A) An applicant for an initial license or initial license designated as a supervised practice license as a genetic counselor shall submit an application under oath in the matter prescribed by the board and provide such other facts and materials as the board requires.

(B) No application shall be considered filed, and shall not be reviewed, until the non-refundable application fee provided for in division (A) of section 4778.03 of the Revised Code has been received by the board.

(C) All application materials submitted to the board by applicants may be thoroughly investigated. The board may contact individuals, agencies, or organizations for recommendations or other information about applicants as the board deems necessary. Applicants may be requested to appear before the board or a representative thereof as part of the application process.

(D) An application for an initial license shall be considered to be complete when all of the following requirements are met:

(1) The application fee provided in section 4778.03 of the Revised Code and all documentation required to demonstrate compliance with division (B) of section 4778.03 of the Revised Code has been received by the board;

(2) The applicant has complied with the requirements of paragraph (A) of rule ~~4778-2-02~~ 4731-4-02 of the Administrative Code and the board has received the results of the criminal records checks;

(3) The board is not conducting an investigation, under section 4778.18 of the Revised Code, of evidence appearing to show that the applicant has violated section 4778.14 of the Revised Code or applicable rules adopted by the board.

(E) An application for an initial license designated as a supervised practice license shall be considered to be complete when all of the following requirements are met:

(1) The applicant has complied with the requirements of paragraph (D) of this rule, except that the applicant is not required to demonstrate certification as a genetic counselor;

(2) The board has received documentation that the applicant is in active candidate status with the American board of genetic counseling.

(F) If an applicant fails to complete the application process within six months of initial

application filing, the board may notify the applicant in writing of its intention to consider the application abandoned. If no response to that notice is received by the board within thirty days, the board shall consider the application as abandoned and no further processing shall be undertaken with respect to that application.

4778-1-03 **Special activity license.**

(A) "Current unrestricted license," as that phrase is used in section 4778.09 of the Revised Code and this rule, means a license or other authority to practice that was issued by the appropriate entity or governmental body of another state or territory which lawfully permits the applicant to practice as a genetic counselor without governmental restrictions or limitations.

(B) The secretary of the board or, in his or her absence, another member of the board designated by the board, shall determine whether an applicant for a special activity license meets the requirements of section 4778.09 of the Revised Code. In making the determination, the secretary of the board or board designee shall take into consideration all of the following:

(1) Whether the practice in this state by the applicant will be associated with a rare disease;

(2) The existence of any information warranting investigation prior to issuance of the special activity license;

(3) Any available information regarding prior performance by the applicant while practicing in this state.

4778-1-05 **Collaboration agreement.**

(A) The collaboration agreement provided for in division (B) of section 4778.11 of the Revised Code shall meet all of the following criteria:

(1) The agreement shall be a written statement identifying and signed by the collaborating physician and genetic counselor who are party to the agreement.

(2) The agreement shall contain a general statement of the procedures, decision criteria, or categories of care that a genetic counselor is to follow when ordering genetic tests or other evaluations.

(3) The agreement shall provide for a selection of the most appropriate, accurate, and cost-effective methods of diagnosis.

(B) A collaborative agreement must be reevaluated at least every two years. If any modification to the agreement is made, the agreement must be re-executed as provided in paragraph (A)(1) of this rule.

(C) A signed copy of the collaborative agreement must be maintained by all parties and available for inspection by the board upon request.

State Medical Board of Ohio

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MEMORANDUM

TO: Jonathan Feibel, M.D., President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Five-Year Rule Review-Chapter 4759, Dietetics

DATE: June 6, 2024

The attached rules were circulated for initial comment with a deadline of March 20, 2024. Two comments were received, which are attached for your review. Karen Charvat of the Ohio Department of Health commented that there was a typographical error in Rule 4759-2-01(A)(7), which has been corrected. Pat McKnight of the Ohio Academy of Nutrition and Dietetics expressed support for the proposed rules.

4759-2-01	**Definitions-Proposed to Amend**
4759-4-01	**Applications-No Change**
4759-4-02	**Preprofessional Experience-Proposed to Amend**
4759-4-03	**Examination-No Change**
4759-4-04	**Continuing Education-No Change**
4759-4-08	**Limited Permit-No Change**
4759-4-09	**License Certificates and Permits-No Change**
4759-5-01	**Supervision of Persons Claiming Exemption-Proposed to Amend**
4759-5-02	**Student Practice Exemption-No Change**
4759-5-03	**Plan of Treatment Exemption-No Change**
4759-5-04	**Additional Nutritional Activities Exemption-Proposed to Amend**
4759-5-05	**Distribution of Literature Exemption-No Change**
4759-5-06	**Weight Control Program Exemption-No Change**
4759-6-01	**Standards of Practice in Nutrition Care-Proposed to Amend**

4759-6-02 **Standards of Professional Performance-Proposed to Amend**

4759-6-03 **Interpretation of Standards-Proposed to Amend**

4759-9-01 **Severability-No Change**

After review of the rules, some technical amendments to Rules 4759-2-01, 4759-6-01, 4759-6-02, and 4759-6-03 are proposed to ensure that the scope of practice permitted by the rules does not exceed the statutory authority.

The additional changes are outlined in the proposed rules, and set forth below, with the new proposed language in bold and underlined..

4759-2-01 Definitions

The following meanings apply to all rules promulgated by the state medical board of Ohio, unless a specific paragraph explicitly defines or uses the word or term in a different manner **subject to the laws of Chapter 4759 of the Revised Code, including section 4759.01 of the Revised Code defining the practice of dietetics.**

(I) "Medical nutrition therapy" means the evidence-based application of the nutrition care and process and use of specific nutrition services to treat, or rehabilitate an illness, injury, or condition. Medical nutrition therapy includes nutrition assessment or re-assessment, nutrition diagnosis, nutrition~~,~~ intervention **through a recommendation or referral to a qualified prescriber under the laws of this state**, nutrition monitoring and evaluation **within the scope of practice of dietetics as defined in section 4759.01 of the Revised Code.** ~~education, and counseling.~~

4759-6-01 Standards of practice in nutrition care.

The standards of practice in nutrition care provide a common understanding about the profession's minimum expectations for practice, and form a basis for self-evaluation and improvement and an expectation about nutritional care and service delivery. The standards of practice in nutrition care are comprised of four standards representing the four steps of the nutrition care process.

The "nutrition care process" is a systematic problem-solving method that dietitians may use to critically think and make decisions when providing medical nutrition therapy or to address nutrition related problems and provide safe, effective, high quality nutrition care **within the scope of practice of dietetics as defined in section 4759.01 of the Revised Code.**

The nutrition care process shall consist of four distinct, but interrelated steps including nutrition assessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation

. . .

(B) The licensee determines a nutrition diagnosis to identify and label specific nutrition problem(s) that the dietitian is responsible for treating. (1) "Nutrition diagnosis" is the identification and labeling that describes an actual occurrence, risk of, or potential for developing, a nutritional problem that dietetics

practitioners are responsible for treating independently **within the scope of practice of dietetics as defined in section 4759.01 of the Revised Code.**

. . .

(C) **Within the scope of practice of dietetics as defined in section 4759.01 of the Revised Code,** ~~**The**~~ **the** licensee utilizes nutrition intervention as the third step in the nutrition care process to identify and implement appropriate, purposefully planned actions designed with the intent of changing a nutrition-related behavior, risk factor, environmental condition or aspect of health status for an individual, target group, or the community at large.

. . .

(3) "Implementation of the nutrition intervention" is the action phase that includes carrying out and communicating the plan of care, continuing data collection, and revising the nutrition intervention strategy, as warranted, based on the patient / client response **within the scope of practice of dietetics as defined in section 4759.01 of the Revised Code.**

(4) **Within the scope of practice of dietetics as defined in section 4759.01 of the Revised Code** ~~**The**~~ **the** licensee performs the interventions or assigns**, recommends, or refers** the nutrition care that other competent practitioners may provide in accordance with federal, state and local laws and regulations.

4759-6-02 Standards of professional performance.

Subject to the laws in Chapter 4759 of the Revised Code, every ~~**Every**~~ licensee shall comply with the following standards of professional performance consistent with the June 1, 2018 "Code of Ethics for the Nutrition and Dietetics Profession" and "2024 Scope and Standards of Practice for the Registered Dietitian Nutritionist" adopted by the academy of nutrition and dietetics which are ~~is~~ available from the website of the state medical board at the following link: https://med.ohio.gov.

4759-6-03 Interpretation of standards.

The standards in the chapter shall be interpreted in a manner consistent with the laws in Chapter 4759 of the Revised Code. Subject to the requirements of these laws, the ~~**The**~~ standards in this chapter are interpreted in a manner consistent with the "Revised ~~2017~~ 2024 Scope and Standards of Practice ~~in Nutrition Care and Standards of Professional Performance~~ for the Registered Dietitian Nutritionists" adopted by ~~the academy of nutrition and dietetics,~~ "The Academy of Nutrition and Dietetics",which is available from the website of the state medical board at the following link: https://www.med.ohio.gov.

Requested Action: Approve filing rules, as amended with Common Sense Initiative.

From:	Morgan, Julia
To:	Anderson, Kimberly
Subject:	FW: 4759-2, 4759-4, 4759-5 and 4759-6 Initial Rules review.
Date:	Tuesday, March 5, 2024 8:29:31 AM
Attachments:	image001.png image002.png image003.png image004.png image005.png image006.png image007.png

---

Fyi

Julia L. Morgan
Administrative Assistant, Legal
State Medical Board of Ohio
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(614) 466-4999
Julia.morgan@med.ohio.gov
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From: Charvat, Karen <Karen.Charvat@odh.ohio.gov>
Sent: Tuesday, March 5, 2024 8:28 AM
To: Morgan, Julia <Julia.Morgan@med.ohio.gov>
Cc: Alwood, Amy <Amy.Alwood@odh.ohio.gov>; Haviland, Breanne <Breanne.Haviland@odh.ohio.gov>; Shepherd, Corey <Corey.Shepherd@odh.ohio.gov>
Subject: RE: 4759-2, 4759-4, 4759-5 and 4759-6 Initial Rules review.

Hello Julia,

Thank you for sending these. The only comment I have is 2759-2-01 (A) (7) has a typo. “includin enteral and parenteral” Including is missing the g.

Thank you,

Karen

Karen Charvat, MBA, RD, LD, CLS
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From: Morgan, Julia <Julia.Morgan@med.ohio.gov>
Sent: Monday, March 4, 2024 4:39 PM
To: Charvat, Karen <Karen.Charvat@odh.ohio.gov>; Haviland, Breanne <Breanne.Haviland@odh.ohio.gov>; Shepherd, Corey <Corey.Shepherd@odh.ohio.gov>; Alwood, Amy <Amy.Alwood@odh.ohio.gov>; Dipasquale, Anita <ADiPasquale@nursing.ohio.gov>; Abby Benjamin <benjamin@sppgrp.com>; Alvin Zachariah <alzach@aol.com>; Aneta Homer MD <ahomer@southwoodshealth.com>; Anna Ruzicka <aruzicka@amcno.org>; Baker, Janet <JanetBaker@foresthills.edu>; Barry T. Doyle (todoyle@aol.com) <todoyle@aol.com>; Bruce B. Whitman (bbwhitmanlaw@aol.com) <bbwhitmanlaw@aol.com>; Mcnamee, Cameron <Cameron.McNamee@pharmacy.ohio.gov>; Damion Clifford <dclifford@arnlaw.com>; Daniel Zinsmaster (daniel.zinsmaster@dinsmore.com) <daniel.zinsmaster@dinsmore.com>; David Paragas <david.paragas@btlaw.com>; Deborah R. Lydon (lydon@dinslaw.com) <lydon@dinslaw.com>; Elaine M. Hiatt PhD <Ehiatt@AIAM.edu>; Eric Vinyard <eric.vinyard@hickspartners.com>; Greg Warren <g.warren@columbusstrategygroup.com>; J. Reichman <jreichman@kkmhealthcare.com>; James Leo <jjleoincolumbus@yahoo.com>; James McGovern (jmcgovern@grafflaw.com) <jmcgovern@grafflaw.com>; Jeffrey Jurca (jjurca@jurcalashuk.com) <jjurca@jurcalashuk.com>; Jennifer Armstrong <jenkarmstrong@hotmail.com>; Joe Feltes <JFeltes@BDBLAW.com>; John R. Irwin <John@johnrirwin.com>; Kay Mavko <kmavko@columbus.rr.com>; Levi Tkach <levi@grafflaw.com>; Lori Herf <LHerf@bakerlaw.com>; M. D. Roland Benton <rbmd_99@yahoo.com>; Mabe, Aaron <Aaron.Mabe@med.ohio.gov>; Marcus Blackstone <marcus_blackstone@bshsi.org>; Matt Harney <mattharney@ohiodo.org>; Mike Mathy OFAMA <mmathy@ohfama.org>; Patricia Weisbach <Patricia_Weisbach@trihealth.com>; patrick@americanmedspa.org; Reardon, Jill <Jill.Reardon@med.ohio.gov>; Shannon Urena <shannonurena1@gmail.com>; Tuch, Socrates <Socrates.Tuch@odh.ohio.gov>; Stefanie Frank <sf@stateside.com>; Steven Greer <sgreer6@kent.edu>; Thomas W. Hess (thess@dinslaw.com) <thess@dinslaw.com>; Jenkins, Vicki

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Cc: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject: 4759-2, 4759-4, 4759-5 and 4759-6 Initial Rules review.

PROPOSED RULES: Seeking comments on the Medical Board's initial review of rules

The State Medical Board of Ohio seeks public input on proposed rules several times during the rule-making process. Public input is sought after the Medical Board has conducted its initial review of rules, after rules are filed with the Common Sense Initiative Office, and at the public hearing that occurs after the rules are formally filed with the Joint Committee on Agency Rule Review.

The Medical Board's initial review of rules may result in a proposal to amend current rules, rescind current rules, make no changes to current rules, and/or adopt new rules. Comments received will be reviewed and possibly result in changes to the initially proposed language before the rules are then filed with the Common Sense Initiative Office.

At this time, public comment is being sought on the proposed language for the following rules. The rules are available on the Medical Board's website at med.ohio.gov/laws-and-regulations/rules/newly-adopted-and-proposed-rules.

4759-2-01	**Definitions-Proposed to Amend**
4759-4-01	**Applications-No Change**
4759-4-02	**Preprofessional Experience-Proposed to Amend**
4759-4-03	**Examination-No Change**
4759-4-04	**Continuing Education-No Change**
4759-4-08	**Limited Permit-No Change**
4759-4-09	**License Certificates and Permits-No Change**
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4759-6-02	**Standards of Professional Performance-Proposed to Amend**
4759-6-03	**Interpretation of Standards-Proposed to Amend**
4759-9-01	**Severability-No Change**

Deadline for submitting comments: **March 20, 2024**

Comments to: Kimberly Anderson
State Medical Board of Ohio
Kimberly.Anderson@med.ohio.gov

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State Medical Board of Ohio

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From: Mcknightp
To: Anderson, Kimberly
Date: Monday, March 4, 2024 6:15:22 PM

Kim -- Of course I approve these. Thanks for using Kay Mavko's input on these.
thanks. pat

Pat McKnight, MS,RDN, LD.
State Policy -- Ohio Academy of Nutrition and Dietetics
Professor Emeritus, Mt. Carmel College of Nursing
mcknightp@aol.com

4759-2-01 **Definitions.**

The following meanings apply to all rules promulgated by the state medical board of Ohio, unless a specific paragraph explicitly defines or uses the word or term in a different manner subject to the laws of Chapter 4759 of the Revised Code, including section 4759.01 of the Revised Code defining the practice of dietetics.

(A) "~~Nutritional~~ Nutrition assessment" means the ~~integrative evaluation of nutritionally relevant data~~systematic approach for collecting, classifying, and synthesizing relevant data to develop an individualized nutritional care plan. These data may include:

(1) Nutrient intake;

(2) Anthropometric measurements;

(3) Biochemical values;

(4) Physical and metabolic parameters;

(5) Socio-economic factors;

(6) Current medical diagnosis and medications; and

(7) Pathophysiological processes.

The mere collection of these data for use in assessment is not nutritional assessment and does not require a dietitian licensed under section 4759.06 of the Revised Code. Nutrition assessment is an on-going dynamic process and includes re-assessment, analysis of client or community needs and provides the foundation for nutrition diagnosis and nutritional recommendations including enteral and parenteral nutrition.

(B) "Nutritional counseling" means the advising of individuals or groups regarding nutritional intake by integrating information from the nutritional assessment with information on food and other sources of nutrients and meal preparation consistent with cultural background and socioeconomic status.

The distribution by an individual of written information prepared by a licensee is not nutritional counseling, and any person distributing the written information need not be licensed under section 4759.06 of the Revised Code.

(C) "Nutritional education" means a planned program based on learning objectives with expected outcomes designed to modify nutrition-related behaviors. This does not

prohibit an unlicensed individual from providing general non-medical nutrition information as defined in paragraph (M) of rule 4759-2-01 of the Administrative Code if the person does not violate division (B) of section 4759.02 of the Revised Code.

(D) "Nutritional care standards" means policies and procedures pertaining to the provision of nutritional care in institutional and community settings.

(E) "Nutritional care" means the application of the science of nutrition in the health and disease of people.

(F) "Board" means the state medical board of Ohio.

(G) "Commission" means "The Commission on Dietetic Registration."

(H) "The Academy" means "The Academy of Nutrition and Dietetics."

(I) "Medical nutrition therapy" means the evidence-based application of the nutrition care and process and use of specific nutrition services to treat, or rehabilitate an illness, injury, or condition. Medical nutrition therapy includes nutrition assessment or re-assessment, nutrition diagnosis, nutrition, intervention, through a recommendation or referral to a qualified prescriber under the laws of this state, nutrition monitoring and evaluation.within the scope of practice of dietetics as defined in section 4759.01 of the Revised Code. ~~education, and counseling.~~

(J) "Council on postsecondary accreditation" is synonymous with its successors the "Commission on recognition of post-secondary accreditation." and the "Council for higher education accreditation ("CHEA")."

(K) For purposes of division (B)(2) of section 4759.02 of the Revised Code, the terms "Nutritionist," "Nutrition counselor" and like terms tend to indicate the person is practicing dietetics.

(L) "High nutritional risk" means, but is not limited to, an individual to whom one or more of the following apply:

(1) Has a diagnosis of or presence of risk factors for malnutrition, dehydration, anemia, malabsorption disorders, vitamin and mineral deficiencies;

(2) Receives enteral or parenteral nutrition;

(3) Has pressure ulcer(s), open wounds(s), or non-healing wound(s);

(4) Significantly low albumin or hemoglobin levels, or elevated blood urea nitrogen and electrolyte imbalances;

(5) Severe chewing or swallowing problems;

(6) Consistently poor food/fluid intakes;

(7) Individuals who are less than ninety per cent of standard weight for height, or who exhibit significant weight changes as defined by accepted practice guidelines;

(8) Decreased activities of daily living (ADL);

(9) Decreased cognitive ability;

(10) A pregnant female who was fifteen years of age or less at the time of conception;

(11) Infants who are small for gestational age, or a pre-term infant of low birth weight.

(M) "General non-medical nutrition information" means information on the following:

(1) Principles of good nutrition and food preparation;

(2) Food to be included in the normal daily diet;

(3) The essential nutrients needed by the body;

(4) Recommended amounts of the essential nutrients;

(5) The actions of nutrients on the body;

(6) The effects of deficiencies or excesses of nutrients; or

(7) Food and supplements that are good sources of essential nutrients.

(N) “Accreditation Council for Education in Nutrition and Dietetics (“ACEND”)” of the Academy of Nutrition and Dietetics is the accrediting agency for didactic education

and preprofessional experience programs that prepare students for careers as dietitians. Dietetics education programs voluntarily apply to the ACEND for program accreditation by submitting applications demonstrating compliance with the accreditation standards.

4759-4-01 **Applications.**

(A) Each applicant for initial licensure or renewal of a license or limited permit shall submit to the board an application which demonstrates compliance with sections 4759.05 and 4759.06 of the Revised Code and this chapter. This application shall be submitted under oath in the manner determined by the board, and provide such other facts and materials as the board requires. No application shall be considered submitted to the board until the appropriate fee has been received by the board. Application fees are not refundable.

(B) No application for a license or permit submitted to the board shall be considered complete until the applicant has complied with the requirements of rule 4731-4-02 of the Administrative Code and the board has received the results of the criminal records checks.

(C) If an applicant fails to complete the application process within six months of initial application filing, the board may notify the applicant in writing of its intention to consider the application abandoned. If no response to that notice is received by the board within thirty days, the board shall consider the application as abandoned and no further processing shall be undertaken with respect to that application.

(D) Each applicant who is not a registered dietitian (RD) must forward an academic transcript from all degree granting institutions of higher education directly to the board or submit an official "student issued" copy.

(E) For the purpose of proving accreditation of a course of study at a foreign institution, an applicant shall have the applicant's academic credentials independently validated as equivalent by an accreditation agency that is recognized by the "Council for Higher Education Accreditation," or its predecessors, or have the applicant's academic credentials independently validated by an agency specializing in education evaluations which is acceptable to the board. A copy of the validation shall be attached to the application as part of the application.

(F) A licensee shall notify the board of a change of address providing at least a new address, telephone number, and signed request for the change. A licensee shall notify the board of a change of name by providing legal evidence of the name change and a signed request for the change.

(G) All applications, statements and documents submitted shall become the property of the board. No application being investigated under section 4759.07 of the Revised Code, may be withdrawn without approval of the board.

4759-4-02 **Preprofessional experience.**

(A) An applicant shall successfully complete a preprofessional practice ~~dietetic~~ experience in dietetics that is accredited ~~approved~~ by the Accreditation Council for Education in Nutrition and Dietetics ("ACEND") of "The Academy of Nutrition and Dietetics" and is at least equivalent to the requirement for such programs adopted by "The Commission On Dietetic Registration."

(B) Doctoral degree alternative.

As an alternative to the requirements in paragraph (A) of this rule, the holder of a doctoral degree may meet the preprofessional dietetic experience requirement by successfully completing a planned program of continuous experience in dietetic practice of not less than ~~nine hundred~~one thousand hours under the supervision of a licensed dietitian in this state or a registered dietitian provided all the following conditions are satisfied:

(1) The applicant holds the doctoral degree from an accredited institution;

(2) The applicant has, as part of successfully completing either a baccalaureate or higher degree from an accredited institution, a major in any of the following subjects: human nutrition, food and nutrition, dietetics, food systems management, or public health nutrition;

(3) The applicant has submitted the program to the board for its approval and received approval prior to engaging in the planned program;

(4) The experience meets requirements that are at least equivalent to the requirements adopted by "The Commission On Dietetic Registration"; and

(5) Following completion of the program, the applicant shall submit a certificate of completion signed by the dietitian who supervised the program.

For purposes of this paragraph, an "accredited institution" is either: an institution accredited to grant the degree described in this paragraph by an accrediting agency that is recognized by the "Council for Higher Education Accreditation" or its predecessors; or an institution in a foreign country when the applicant presents evidence that the doctoral degree has been validated as equivalent to a degree under this paragraph by an institution accredited for such degrees in accordance with this paragraph or; by an agency specializing in educational credential evaluations which is acceptable to the board.

4759-4-03 **Examination.**

(A) As a prerequisite to the issuance of an initial license, the applicant shall provide evidence of passing the examination designated in paragraph (B) of this rule.

(B) The board selects and approves of the examination for dietitians offered by "The Commission On Dietetic Registration."

4759-4-04 **Continuing education.**

(A) An applicant for renewal or restoration of a license shall demonstrate compliance with the continuing education/professional development requirements of this rule.

(B) An applicant for license renewal or restoration shall:

(1) If licensee is a registered dietitian, certify completion of the continuing education required to hold current registration with the commission on dietetic registration, and complete one hour of ethics or laws, rules, and regulations governing the practice of dietetics in the two-year renewal period. These continuing education hours shall be from activities approved by the commission on dietetic registration, academy of nutrition and dietetics, or the Ohio academy of nutrition and dietetics; or

(2) If licensee is not a registered dietitian, certify the completion of thirty hours of continuing education completed during the two-year renewal period. At least one hour in each renewal period shall relate to ethics or laws, rules, and regulations governing the practice of dietetics. These continuing education hours shall be from activities approved by the commission on dietetic registration, academy of nutrition and dietetics, or the Ohio academy of nutrition and dietetics.

In addition for each biennial renewal period, a licensee that is not a registered dietitian shall use and document a learning process for that renewal period that is consistent with the commission on dietetic registration. Specifically, the licensee that is not a registered dietitian shall document the following: self-reflection on competencies and learning needs, development of a learning plan with goals to maintain and improve on existing competencies and/or develop competencies in new areas or areas of learning deficiency; and progress on the learning plan documented through successful completion of activities in the areas specified in the learning plan. This learning plan must be documented and available to the board upon request pursuant to the audit and disciplinary provisions of divisions (E) and (F) of section 4759.06 of the Revised Code.

(C) All licensees are subject to the audit and disciplinary provisions of divisions (E) and (F) of section 4759.06 of the Revised Code for failure to comply with this rule. Licensees are responsible for retaining records of completion of the continuing education hours required.

4759-4-08 **Limited permit.**

(A) The board may grant a limited permit to a person who has completed the education and preprofessional requirements for licensure upon the following conditions:

(1) The person has filed a completed application for a limited permit and paid the appropriate fee;

(2) The application contains any required statements or transcripts verifying completion of the academic and preprofessional requirements in order to qualify to take the examination for licensure; and

(3) The applicant indicates intent to take the examination for licensure within six months of the issuance of the limited permit.

(B) The permit shall expire if the permit holder fails to take the examination in a timely manner or fails the examination twice.

(C) Limited permits shall expire six months after the date of issuance.

(D) A limited permit may be renewed once.

(E) A limited permit holder who fails the examination must report the results to the board office immediately.

(1) The first time the limited permit holder fails, the limited permit holder shall practice only under the direct supervision of an Ohio licensed dietitian.

(2) The second time the limited permit holder fails, the limited permit expires immediately.

(F) A limited permit shall not be issued to a person who has failed the examination two or more times.

(G) The licensed dietitian who provides direct supervision of a person who has failed the examination and holds a limited permit shall provide sufficient guidance and direction to enable the person to perform competently and to protect the public.

(1) The licensed dietitian shall document a supervision plan for the limited permit holder to include specific goals and strategies for assuring competent entry level practice. The supervising dietitian shall periodically document the limited permit holder’s progress. Documentation shall include, but is not

limited to, dates of conferences, supervisory notes, written evaluations and recommendations. Documentation should be maintained in the licensed dietitian's records and be available upon request of the board.

(2) Direct supervision means that the licensee providing the supervision needs to be readily available by telecommunication, or in person and the licensee must review the work of the supervisee at least every seven days. When reviewing the work of a supervisee, the licensee shall comply with standards for professional responsibility and practice set forth in Chapter 4759-6 of the Administrative Code.

(H) It is the licensed dietitian's responsibility to supervise the limited permit holder and to adequately document that supervision. Failure to do so shall be considered a violation of the minimal standards of care for the licensed dietitian and may result in discipline of the licensed dietitian by the state medical board.

4759-4-09 **License certificates and permits.**

(A) The board shall prepare and provide to each new licensee and limited permit holder a certificate signed by the board's president and secretary, and attested by its seal.

(B) Neither the holder nor anyone else shall make any alteration on a certificate issued by the board.

(C) Official verification letters will be issued by the board upon request only and with payment of the license verification fee specified in section 4759.08 of the Revised Code. Electronic verification of license or limited permit status shall be considered a primary source verification and shall be made available by the board.

4759-5-01 **Supervision of persons claiming exemption.**

For the purposes of the supervision requirement contained in divisions (B) and (E) of section 4759.10 of the Revised Code the dietitian who provides supervision shall be responsible for the supervision of the person claiming exemption from licensure as a dietetic technician, or dietetic technician registered, or nutrition associate and shall provide sufficient guidance and direction as to enable the person to perform competently. These individuals have completed at least a two-year associates degree or higher from a program in dietetic technology or dietetics that has been ~~approved~~accredited by the ~~commission on accreditation~~"Accreditation Council for Education in Nutrition and ~~dietetics~~ Dietetics ~~education~~ of the "Academy of Nutrition and Dietetics." Dietetic technicians registered have also passed the national written examination administered by the commission on dietetic registration and maintain professional development / continuing education requirements for on-going registration.

The licensed dietitian is responsible and accountable for the nutrition care of patients / clients in all healthcare settings and must answer to patients, employers, licensure boards and the legal system if care is compromised.

The licensee shall not delegate the nutrition care process, but may assign tasks within the process to competent exempt practitioners for the purpose of providing the licensee with needed information and communicating with and educating patients / clients.

When supervising a person claiming exemption the licensee shall:

(A) Verify the credentials and competence of each individual exempt practitioner being supervised in the areas of dietetic practice as defined in section 4759.10 of the Revised Code. Those exempt practitioners who are competent to practice beyond minimum standards should be expected to demonstrate initial and on-going competence annually with documentation of successful audits.

The supervising dietitian can establish initial and on-going competency by individual means including but not limited to testing, evaluations, use of decision tree models and peer competency assessment. Engaging in on-going dietetics related continuing education is vital to competent practice.

(B) Provide the person being supervised with guidelines for appropriate assignments as part of the nutritional care process;

(C) Periodically establish performance criteria for the exempt practitioner, then assign tasks appropriately, direct and monitor the individual's practice. The supervising dietitian should compare actual performance with expected performance, document results and take appropriate action;

(D) Maintain written documentation of the initial and on-going competency assessment of the exempt practitioner, supervision being provided and performance of the

individual, including participation in professional development / continuing education equivalent to the requirements of the commission on dietetic registration for dietetic technicians registered.

Documentation shall include, but is not limited to, dates of conferences, supervisory anecdotal notes, written evaluations and recommendations. Documentation should be maintained in the licensee's records and be available upon request of the board.

(E) The licensee shall provide supervision in a manner that protects the public. Direct supervision may be provided on-site, or supervision may be provided indirectly, as long as the licensee is immediately available by phone, e-mail, facsimile or other reliable means.

4759-5-02 **Student practice exemption.**

(A) For purposes of divisions (D)(1) and (D)(2) of section 4759.02 of the Revised Code, a student dietitian may only engage in dietetic practice as defined in division (A) of section 4759.01 of the Revised Code that is a part of the academic or pre-professional program.

(B) In order for student dietetic technicians to become qualified under the exemption for dietetic technicians contained in division (B) of section 4759.10 of the Revised Code, the board recognizes that pre-professional experiences are necessary. For this reason, dietetic practice by a student dietetic technician enrolled in a program that complies with the requirements in division (B) of section 4759.10 of the Revised Code, may be performed provided the student is actively pursuing the degree and the activity is performed under the supervision of a licensed dietitian or registered dietitian. A student dietetic technician may only engage in dietetic practice as defined in division (A) of section 4759.01 of the Revised Code that is a part of the academic or pre-professional program.

(C) When supervising a student dietitian, a dietetic intern, or a student dietetic technician the licensee is responsible for providing appropriate training and guidelines for the student's clinical experiences, including ongoing close review of medical records and monitoring of student work performance. Documentation of such should be maintained in the licensee's records.

4759-5-03 **Plan of treatment exemption.**

For purposes of the exemption from licensure contained in division (F) of section 4759.10 of the Revised Code, a person when acting under the direction and supervision of a professional licensed under Title 47 of the Revised Code, need not be a licensed dietitian if the person is executing a plan of treatment authorized by and within the scope of practice of the supervising licensed professional. The written plan of treatment shall include orders, goals, objectives, and appropriate treatments. Frequency of treatment and response to interventions shall be monitored and reviewed by the licensed practitioner. The licensed practitioner shall initiate the treatment plan and shall be on site when the plan is carried out by the unlicensed person.

4759-5-04 **Additional nutritional activities exemption.**

For purposes of division (D) of section 4759.10 of the Revised Code, the board hereby permits the woman, infant, and children's program which is part of the Ohio department of health and known as "W.I.C.", to designate a person to engage in providing such additional nutritional activities as are necessary to operate its programs, providing reasonable efforts to obtain the services of a licensee have failed. ~~The department shall file the designation indicating the time period with the board. The designation shall expire at the end of one hundred eighty days. The designation may be renewed for additional one-hundred-eighty-day periods by action of the board.~~

4759-5-05 **Distribution of literature exemption.**

For purposes of division (G) of section 4759.10 of the Revised Code, the free distribution of literature includes its sale.

4759-5-06 **Weight control program exemption.**

For purposes of the exemption from licensure contained in division (J) of section 4759.10 of the Revised Code, a person presenting a general program of instruction for weight control need not be a licensed dietitian provided the general program of weight control is approved in writing by a licensed dietitian, physician licensed under Chapter 4731. of the Revised Code to practice medicine or surgery or osteopathic medicine or surgery, a person licensed in another state and approved by the board as having substantially equivalent licensure requirements as Ohio, or a registered dietitian.

A "general program of weight control" is a program designed for one or more population groups in order to achieve or maintain a healthy weight. It is not based on an individual nutrition assessment and does not provide medical nutrition therapy (MNT) as defined in rule 4759-2-01 of the Administrative Code. The program includes the diet plan and any information provided to customers including written guidelines for instruction to customers.

Persons presenting an approved general program of weight control are to adhere to the approved program content. The program shall be reviewed for re-approval in writing at least every two years.

4759-6-01 **Standards of practice in nutrition care.**

The standards of practice in nutrition care provide a common understanding about the profession's minimum expectations for practice, and form a basis for self-evaluation and improvement and an expectation about nutritional care and service delivery. The standards of practice in nutrition care are comprised of four standards representing the four steps of the nutrition care process.

The "nutrition care process" is a systematic problem-solving method that dietitians may use to critically think and make decisions when providing medical nutrition therapy or to address nutrition related problems and provide safe, effective, high quality nutrition care within the scope of practice of dietetics as defined in section 4759.01 of the Revised Code.

The nutrition care process shall consist of four distinct, but interrelated steps including nutrition assessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation.

(A) The licensee uses accurate and relevant data and information to perform nutrition assessment and identify nutrition-related problems, as the foundation for nutrition diagnosis, the second step of the nutrition care process.

(1) "Nutrition assessment" means the same as "nutritional assessment" defined in paragraph (A) of rule 4759-2-01 of the Administrative Code.

(2) A nutrition assessment is initiated by referral and / or screening of individuals or groups for nutrition risk factors.

(3) The licensee systematically obtains, verifies and interprets data in order to make decisions about the nature and cause of nutrition-related problems.

(4) Nutrition assessment is an ongoing, dynamic process that involves not only initial data collection, but also reassessment and analysis of client or community needs.

(5) Problems that require consultation with or referral to another provider are recognized.

(6) Documentation and communication of nutritional assessment shall be complete, relevant, accurate and timely.

(B) The licensee determines a nutrition diagnosis to identify and label specific nutrition problem(s) that the dietitian is responsible for treating.

(1) "Nutrition diagnosis" is the identification and labeling that describes an actual occurrence, risk of, or potential for developing, a nutritional problem that

dietetics practitioners are responsible for treating independently within the scope of practice of dietetics as defined in section 4759.01 of the Revised Code..

(2) The nutrition diagnosis is not a medical diagnosis. It results following nutrition assessment and the clustering, analysis, and synthesis of data and demonstrates a link to determining goals for outcomes, selecting appropriate interventions and tracking progress in attaining expected outcomes.

(3) Documentation of nutrition diagnosis(es) shall be relevant, accurate and timely and shall be revised and updated as additional assessment data become available.

(C) Within the scope of practice of dietetics as defined in section 4759.01 of the Revised Code, the ~~The~~ licensee utilizes nutrition intervention as the third step in the nutrition care process to identify and implement appropriate, purposefully planned actions designed with the intent of changing a nutrition-related behavior, risk factor, environmental condition or aspect of health status for an individual, target group, or the community at large.

(1) "Nutrition Intervention" is a specific set of activities and associated materials used to address the problem; purposely planned actions designed with the intent of changing a nutrition-related behavior, risk factor, environmental condition, or aspect of health status for an individual, target group, or the community at large. It involves selection, planning, and implementing appropriate actions to meet patient / client / group's nutrition needs.

(2) "Intervention planning" involves prioritizing the nutrition diagnoses, conferring with the patient / client / and / or others, reviewing practice guides and policies, and setting goals and defining the specific nutrition intervention strategy.

(3) "Implementation of the nutrition intervention" is the action phase that includes carrying out and communicating the plan of care, continuing data collection, and revising the nutrition intervention strategy, as warranted, based on the patient / client response within the scope of practice of dietetics as defined in section 4759.01 of the Revised Code.

(4) Within the scope of practice dietetics as defined in section 4759.01 of the Revised Code, the ~~The~~ licensee performs the interventions or assigns, recommends or refers the nutrition care that other competent practitioners may provide in accordance with federal, state and local laws and regulations.

(D) The licensee monitors and evaluates indicators and outcomes data directly related to the nutrition diagnosis, goals and intervention strategies to determine the progress made in achieving desired outcomes of nutrition care and whether planned interventions should be continued or revised.

(1) "Nutrition monitoring and evaluation" is the fourth step of the nutrition care process. ~~Monitoring~~ Nutrition monitoring specifically refers to the review and measurement of the patient / client / group's status at a scheduled (preplanned) follow-up point with regard to the nutrition diagnosis, intervention plans / goals and outcomes.~~, whereas evaluation~~ Evaluation is the systematic comparison of current findings with previous status, intervention goals, or a reference standard. Monitoring and evaluation use selected outcome indicators (markers) that are relevant to the patient / client / group's defined needs, nutrition diagnosis, nutrition goals, and disease state.

(2) The licensee uses standard nutrition care outcome indicator(s) to measure outcomes.

(3) Monitoring data should be compared with the nutrition prescription / goals / or reference standards to evaluate impact of the sum of all interventions on overall patient / client health outcomes.

(4) Documentation of nutrition monitoring and evaluation shall be comprehensive, specific, accurate, relevant and timely and reflect the indicators measured, results and method for obtaining measurement. The criteria to which the indicator is compared and factors facilitating or hampering progress should be referenced in support of positive or negative outcomes. ~~Future plans~~Plans for nutrition care, monitoring and follow-up or discharge should be included.

(5) Ensures communication of nutrition plan of care and transfer of nutrition-related data between care settings as needed including acute care, home healthcare, ambulatory care, community care, and long-term care facility.

4759-6-02 **Standards of professional performance.**

Subject to the laws in Chapter 4759 of the Revised Code, every ~~Every~~ licensee shall comply with the following standards of professional performance consistent with the June 1, 2018 "Code of Ethics for the Nutrition and Dietetics Profession" and "2024 Scope and Standards of Practice for the Registered Dietitian Nutritionist" adopted by the academy of nutrition and dietetics which are~~is~~ available from the website of the state medical board at the following link: https://med.ohio.gov.

(A) Credentials.

(1) The licensee shall accurately present professional qualifications and credentials.

(2) The licensee shall permit use of that licensee's name for the purpose of certifying that dietetic services have been rendered only if the licensee has provided or supervised those services.

(B) Provision of service.

The licensee shall provide professional service based on client expectations and needs. Quality service is provided, facilitated and promoted based on the licensee's knowledge, experience and understanding of client needs and expectations.

(1) The licensee shall avoid discrimination on the basis of factors that are irrelevant to the provision of professional services, including, but not limited to cultural differences, race, creed, sex, age, or handicap.

(2) The licensee shall make evidence-based practice decisions, taking into account the unique values and circumstances of the patient or client and community, in combination with the licensee's expertise and judgment. ~~assure that sufficient information is available to enable a client to establish mutual goals and make informed decisions.~~

(C) Quality in practice.

(1) The licensee shall systematically evaluate the quality of service and improve practice based on evaluation results.

(2) Quality practice requires regular performance evaluation and continuous improvement.

(3) The licensee shall adhere to acceptable standards for that licensee's area of practice and be designated to deliver services as approved by their facility. The authority and privilege to practice within the scope shall be consistent

with all state and federal laws and rules governing the practice of dietetics.

(4) The licensee shall generate, interpret and effectively apply evidence based interventions substantiated by research.

(5) The licensee recognizes the value of health equity in all forms of interaction when delivery, care or services to colleagues, customers, students and interns and when contracting with stake holders.

(D) Competence and accountability.

(1) The licensee shall assume and maintain responsibility and accountability for personal competence in practice and engage in lifelong learning. Competent and accountable practice includes continuous acquisition of knowledge and skill development.

(a) The licensee shall establish performance criteria, compare actual performance with expected performance, document results and take appropriate action.

(b) The licensee shall conduct self-assessment of strengths and weaknesses at regular intervals and develop, implement and evaluate an individual plan for practice based on assessment of client needs, current knowledge, and clinical experience~~.~~, formal and informal input from colleagues, interprofessional teams, and supervisors.

(2) ~~The licensee shall maintain knowledge and skills required for continued professional competence.~~

~~(3)~~(2) The licensee shall recognize the limits of that licensee's qualifications and collaborate with an interprofessional team to facilitate referrals when individual needs exceed the licensee's scope of practice. ~~seek counsel or make referrals as appropriate.~~

(E) Conflict.

(1) The licensee shall remain free of conflict of interest while fulfilling the objectives and maintaining the integrity of the dietetic profession.

(2) The licensee shall advance and promote the profession while maintaining professional judgment, honesty, integrity, loyalty, and trust to colleagues,

clients and the public.

(F) Endorsement.

The licensee shall promote or endorse products only in a manner that is true and not misleading~~.~~,and shall disclose any financial interests in products or services that are recommended.

(G) Communication and application of knowledge.

The licensee shall effectively apply knowledge and communicate with others to achieve common goals by effective sharing and application of their unique knowledge and skills in food, human nutrition and management services.The licensee communicates consistent with the Health Insurance Portability and Accountability Act of 1996, Pub.L.No. 104-191.

(H) Utilization and management of resources.

The licensee shall provide quality services ~~use resources~~ effectively and efficiently.

The licensee shall use a systematic approach to identify, monitor, analyze and justify the use of time, money, facilities, staff and other resources while considering safety, effectiveness and cost in planning and delivering interventions.

(I) Approval of a general program of weight control.

A "general program of weight control" as defined in rule 4759-5-06 of the Administrative Code must be approved by either a registered or licensed dietitian or physician licensed in Ohio. For purposes of division (J) of section 4759.10 of the Revised Code, the licensee shall provide written approval of all components of the general program of weight control and assume responsibility for the following:

(1) Guidelines for instruction: program content and written step-by-step information that the presenter provides to customers to enable them to follow the meal plan and other aspects of a general program of weight control.

(2) Meal plans: general categories or groups of foods and suggested combinations of specific foods. Meal plans shall not be individualized for specific persons, conditions, or disease states.

(3) Handouts: any information distributed in conjunction with the general program of weight control.

(4) Supplements: products, including vitamins, minerals, herbs and other substances used as part of, or an enhancement to, a general program of weight control. The use of these products shall be substantiated by current scientific evidence.

(J) Supervision.

When providing supervision of another for purposes of division (G) of section 4759.06 and divisions (B) and (E) of section 4759.10 of the Revised Code, and rule 4759-5-02 of the Administrative Code, a licensee shall assume responsibility for the supervision in a manner that protects the public.

(K) Compliance.

The licensee shall comply with all laws and regulations concerning the profession, but shall seek to change them if the laws or regulations are inconsistent with the best interest of the public and the profession. The licensee:

(1) Shall accept the obligation to protect society and the profession by upholding the standards of practice and standards of professional performance; and

(2) Shall report alleged violations of the laws, rules and standards to the state medical board.

(L) Interpretation of information and application of research.

(1) The licensee shall present substantiated information and interpret controversial information, including limitations, potential bias, and reliability without personal bias, recognizing that a legitimate difference of opinion may exist.

(2) The licensee shall apply, participate in, or generate research to enhance practice and to improve safety and quality of dietetic practice and services.

(M) Confidentiality.

The licensee shall maintain information consistent with legal obligations and client confidentiality.

(N) Professional conduct.

(1) The licensee shall conduct all practices with honesty, integrity, and fairness; and

(2) The licensee shall make and fulfill professional commitments in good faith; and

(3) The licensee shall inform the public and colleagues of services by use of factual information.

(4) The licensee shall make reasonable efforts to avoid bias in professional evaluation.

(O) A violation of any provision of this rule, as determined by the board, shall constitute "a departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established" as that clause is used in division (A)(11) of section 4759.07 of the Revised Code.

4759-6-03 **Interpretation of standards.**

The standards in the chapter shall be interpreted in a manner consistent with the laws in Chapter 4759 of the Revised Code. Subject to the requirements of these laws, the ~~The~~ standards in this chapter are interpreted in a manner consistent with the "Revised ~~2017~~ 2024 Scope and Standards of Practice ~~in Nutrition Care and Standards of Professional Performance~~ for the Registered Dietitian Nutritionists" adopted by ~~the academy of nutrition and dietetics,~~ "The Academy of Nutrition and Dietetics",which is available from the website of the state medical board at the following link: https://www.med.ohio.gov.

4759-9-01 **Severability.**

Each rule of Chapters 4759-1 to 4759-10 of the Administrative Code, and every part of each rule is declared to be an independent rule, and the holding of any rule or part thereof to be unconstitutional, void, or ineffective for any cause shall not affect the validity or constitutionality of any other rule or part thereof.

State Medical Board of Ohio

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MEMORANDUM

TO: Jonathan Feibel, M.D., President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Office-Based Opioid Treatment Rules (Chapters 4731-33 and 4730-4)

DATE: June 7, 2024

The rules for physicians and physician assistants prescribing opioids for ambulatory withdrawal and office-based opioid treatment were filed with the Common Sense Initiative on April 4, 2024 with comments due by April 19, 2024. Comments were received from the Academy of Medicine of Cleveland and Northern Ohio, UC Health, Ohio Society of Addiction Medicine, Ohio Psychiatric Physician Association, Ohio Wexner Medical Center, and Dennis Helmuth, MD, PhD. The Board also received responses to the comments from the Ohio Board of Nursing and the Ohio Board of Pharmacy. All comments are attached for your review.

Also attached for review is a spreadsheet outlining the substantive comments by rule section with a recommendation.

Finally, draft rules with the recommended proposed amendments are attached for your review. The new language is highlighted in yellow.

Requested Action: Recommend communication to interested parties and Common Sense Initiative regarding recommended amendments.

Comments on Rules in Chapter 4731-33 and 4730-4 By Rule Provision

Rule Provision	Organization	Comments	Recommendation
4731-33-02(E)(2) & 4730-4-02(E)(2)	UC Health; Ohio Society of Adiction Medicine	Clarify that ASAM criteria is for determining location of treatment rather than a practice protocol.	Added language to clarify that ASAM criteria is for determination of patient placement and added language stating that a referral to higher level of care should be made if ambulatory withdrawal is not appropriate or safe for the patient. Eliminated reference to 4th edition.
4731-33-02(E)(8) & 4730-4-02(E)(8)	Ohio Society of Addiction Medicine	Recommend providing more detail that a higher level of care could include a hospital, inpatient medically supervised withdrawal facilities, or outpatient addiction specialty care.	Recommend no change
4731-33-02(E)(11) & 4730-4-02(E)(11)	UC Health; Ohio Society of Adiction Medicine	Recommend revision of language to clarify that all methods of steps to reduce the risk of medication diversion do not have to be completed.	Recommend language change to indicate that one or more of the tools to reduce risk of diversion shall be used.
4731-33-02(F)(5)(c) & 4730-4-02(F)(5)(c)	Ohio Society of Addiction Medicine	Recommend revision of language to clarify that all methods of steps to reduce the risk of medication diversion do not have to be completed.	Recommend language change to indicate that one or more of the tools to reduce risk of diversion shall be used.
4731-33-02(G)(1) & 4730-4-02(G)(1)	Ohio Society of Addiction Medicine	Remove the phrase related to polysubstance dependence.	Recommend removal of phrase related to polysubstance dependence, but add requirement that patient is not at risk for serious withdrawal from substances other than alcohol.
4731-33-02(G)(4)(c) & 4730-4-02(G)(4)(c)	Ohio Society of Addiction Medicine	Recommend revision of language to clarify that all methods of steps to reduce the risk of medication diversion do not have to be completed.	Recommend language change to indicate that one or more of the tools to reduce risk of diversion shall be used.
4731-33-03(A)(3) & 4730-4-03(A)(3)	Academy of Medicine of Cleveland and Northern Ohio; UC Health; Ohio Society of Addiction Medicine	Rescind the requirement for 8 hours of CME related to substance use disorder and addiction every two years.	Recommend no change.
4731-33-03(A)(4) & 4730-4-03(A)(5)	OSU Wexner Medical Center; Ohio Psychiatric Physician Association	Supports clarification that OBOT may be initiated prior to completion of full assessment and lab testing.	No change requested.
4731-33-03(B)(3) & 4730-4-03(B)(3)	UC Health, Ohio Society of Adiction Medicine	Rescind the requirement for patient's written, informed consent because it is not standard of care for medication management and a signed treatment agreement is required.	Recommend removal of separate paragraph related to informed consent and recommend addition of language to (B)(5) that signed treatment agreement documents the patient's consent for treatment.
4731-33-03(C) and 4730-4-03(C)	UC Health, Ohio Society of Adiction Medicine	Recommend revision of requirement to utilize a practice protocol so that clinicians can integrate the latest research into their practice. Also add ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids as an additional acceptable protocol.	Recommend no change
4731-33-03(D) & 4730-4-03(D)	Academy of Medicine of Cleveland and Northern Ohio; OSU Wexner Medical Center; Ohio Psychiatric Physician Association; Ohio Society of Addiction Medicine	Supports changes to behavioral health treatment.	No change requested.
4731-33-03(F)(2) & 4730-4-03(F)(2)	UC Health; Ohio Psychiatric Physician Association; OSU Wexner Medical Center	Rescind paragraphs (F)(2)(a)through (d) to allow for more prescribing of buprenorphine monoproduct.	Recommend no change.
4731-33-03(F)(3) & 4730-4-03(F)(3)	UC Health; Ohio Psychiatric Physician Association	Remove gabapentin from list of medications that should not be co-prescribed with buprenorphine.	Recommend no change.
4731-33-03(F)(5)(a) & 4730-4-03(F)(5)(a)	UC Health; Ohio Society of Adiction Medicine; Ohio Psychiatric Physician Association; OSU Wexner Medical Center	UC Health: Eliminate the requirement for prescriptions to be limited to 14 days for the first 90 days and clarify that the assessment could be via telehealth or delegated to other healthcare professionals other than the prescriber. OSAM: During the first 90 days, the prescription should not exceed 3-week supply. OPPA and OSU Wexner Medical Center: Reconsider limitation of buprenorphine to a 14 day prescription in the first 90 days.	Recommend change that prescriptions shall be limited to a one-month supply for the first 12 months.
4731-33-03(F)(6) & 4730-4-03(F)(6)	Ohio Society of Addiction Medicine	Revise language to allow clinician to select any of the tools to reduce risk of diversion.	Recommend language change to indicate that one or more of the tools to reduce risk of diversion shall be used.
4731-33-03(F)(7) & 4730-4-03(F)(7)	Ohio Academy of Medicine of Cleveland and Northern Ohio; Ohio Society of Addiction Medicine	Supports changes to raise buprenorphine dosage ceiling.	No change requested.

4731-33-03(F)(7) & 4730-4-03(F)(7)	OSU Wexner Medical Center; UC Health; Ohio Psychiatric Physician Association	Supports increasing the maximum daily oral dose to 32 mg but recommend removal of requirement for consultation with addiction specialist for doses exceeding 24 mg per day.	Recommend no change.
4731-33-04(A)(2)(c) & 4730-4-04(A)(2)(c)	UC Health; Ohio Society of Adiction Medicine, OSU Wexner Medical Center	UC Health: Remove requirement for pill counts and remove requirement for specific frequency of urine drug screens. OSAM: Remove requirement for pill counts.OSU Wexner Medical Center: Reconsider specifying the frequency of urine drug screens.	Recommend removal of pill count requirement.

4730-4-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means pharmacotherapy, in a private office or public sector clinic that is not otherwise regulated by practitioners authorized to prescribe outpatient supplies of medications approved by the United States food and drug administration for the treatment of opioid use disorder. OBOT includes treatment with all controlled substance medications approved by the United States food and drug administration for such treatment. OBOT does not include treatment that occurs in the following settings

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) A hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addiction services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body;

(5) A youth services facility, as defined in section 103.75 of the Revised Code; and

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

(B) "SAMHSA" means the United States substance abuse and mental health services administration.

(C) Addiction specialist physician" means a physician who holds one of the following medical subspecialty certifications:

(1) Subspecialty board certification in addiction medicine by the American board of preventative medicine ("ABPM");

(2) Subspecialty board certification in addiction psychiatry by the American board of psychiatry and neurology ("ABPN");

(3) Subspecialty board certification in addiction medicine by the American osteopathic association ("AOA"); or

(4) Certification by the American board of addiction medicine ("ABAM")

(D) "Medications for Opioid Use Disorder or "MOUD" refers to all medications approved by the United States food and drug administration for the treatment of opioid use disorder.

(E) "Substance use disorder" indicates a problematic pattern of substance use leading to clinically significant impairment or distress, as determined by application of the diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition-Text Revision" or "DSM-5-TR."

(F) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(G) For purposes of the rules in this chapter:

(1) "Qualified behavioral healthcare provider" means the following healthcare providers practicing within the scope of the professional license:

(a) Addiction medicine specialist physician or board certified psychiatrist, licensed under Chapter 4731 of the Revised Code;

(b) Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732 of the Revised Code;

(c) Licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, or licensed chemical dependency counselor II, or licensed chemical dependency counselor assistant licensed under Chapter 4758 of the Revised Code;

(d) Professional clinical counselor, licensed professional counselor, licensed independent social worker, licensed social worker, or marriage and family therapist, licensed under Chapter 4757 of the Revised Code;

(e) Advanced practice registered nurse, licensed as a clinical nurse specialist under Chapter 4723 of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center;

(f) Advanced practice registered nurse, licensed as a nurse practitioner under Chapter 4723 of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center; and

(g) Advanced practice registered nurse, licensed under Chapter 4723 of the Revised Code, who holds subspecialty certification as a certified addiction registered nurse-advanced practice issued by the addictions nursing certification board.

(2) Nothing in this paragraph shall be construed to prohibit a physician assistant licensed under Chapter 4730 of the Revised Code who practices under a

supervision agreement with a board certified addiction psychiatrist, board certified addiction medicine specialist, or psychiatrist who is licensed as a physician under Chapter 4731 of the Revised Code, from providing services within the normal course of practice and expertise of the supervising physician, including addiction services, other mental health services, and physician delegated prescriptive services in compliance with Ohio and federal laws and rules.

(H) "Community addiction services provider," has the same meaning as in section 5119.01 of the Revised Code.

(I) "Community mental health services provider" has the same meaning as in section 5119.01 of the Revised Code.

(J) "Induction phase" means the phase of MOUD during which the patient is started on an FDA-approved medication for substance use disorder treatment.

(K) “Stabilization phase” means the period of time following the induction phase, when medication doses are adjusted to target a reduction in substance use disorder symptoms.

(L) “Maintenance phase" means the ongoing period of time when the patient’s medication dose reaches a therapeutic level, allowing the patient to focus on other recovery activities.

(M) "Withdrawal management" is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. Withdrawal management occurs when the patient has a substance use disorder and either evidence of the characteristic withdrawal syndrome produced by withdrawal from that substance, or evidence that supports the expectation that such a syndrome would develop without the provision of medical withdrawal management services. Withdrawal management alone does not constitute completed substance use disorder treatment or rehabilitation.

(N) "Ambulatory withdrawal management" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by trained practitioners authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of substance use disorder. Ambulatory withdrawal management is the provision of medically supervised evaluation, treatment, and referral services without extended onsite monitoring. For purpose of rule 4730-4-02 of the Administrative Code, ambulatory withdrawal management does not include withdrawal management that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) In-patient treatment in a hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addition services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body;

(5) A youth services facility, as defined in section 103.75 of the Revised Code; and

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

4730-4-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means medication-assisted treatment, as that term is defined in this rule, in a private office or public sector clinic that is not otherwise regulated, by practitioners authorized to prescribe outpatient supplies of medications approved by the United States food and drug administration for the treatment of opioid addiction or dependence, prevention of relapse of opioid addiction or dependence, or both. OBOT includes treatment with all controlled substance medications approved by the United Stated food and drug administration for such treatment. OBOT does not include treatment that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) A hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addiction services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body; or

(5) A youth services facility, as defined in section 103.75 of the Revised Code.

(B) "SAMHSA" means the United States substance abuse and mental health services administration.

(C) "Medication-assisted treatment" means alcohol or drug addiction services that are accompanied by medication that has been approved by the United States food and drug administration for the treatment of substance use disorder, prevention of relapse of substance use disorder, or both.

(D) "Substance use disorder" includes misuse, dependence, and addiction to alcohol and/or legal or illegal drugs, as determined by diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition" or "DSM-5."

(E) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(F) For purposes of the rules in Chapter 4730-4 of the Administrative Code:

(1) "Qualified behavioral healthcare provider" means the following who is practicing within the scope of the professional license:

(a) Board certified addictionologist, board certified psychiatrist, or psychiatrist, licensed under Chapter 4731. of the Revised Code;

(b) Licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, or licensed chemical dependency counselor II, or licensed chemical dependency counselor assistant licensed under Chapter 4758. of the Revised Code;

(c) Professional clinical counselor, licensed professional counselor, licensed independent social worker, licensed social worker, or marriage and family therapist, licensed under Chapter 4757. of the Revised Code;

(d) Advanced practice registered nurse, licensed as a clinical nurse specialist under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center;

(e) Advanced practice registered nurse, licensed as a nurse practitioner under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center;

(f) Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732. of the Revised Code;

(g) Advanced practice registered nurse, licensed under Chapter 4723. of the Revised Code, who holds subspecialty certification as a certified addiction registered nurse-advanced practice issued by the addictions nursing certification board.

(2) Nothing in this paragraph shall be construed to prohibit a physician assistant licensed under Chapter 4730. of the Revised Code who practices under a supervision agreement with a board certified addiction psychiatrist, board certified addictionologist, or psychiatrist who is licensed as a physician under Chapter 4731. of the Revised Code, from providing services within the normal course of practice and expertise of the supervising physician, including addiction services, other mental health services, and physician delegated prescriptive services in cmpliance with Ohio and federal laws and

rules.

(G) "Community addiction services provider," has the same meaning as in section 5119.01 of the Revised Code.

(H) "Community mental health services provider" has the same meaning as in section 5119.01 of the Revised Code.

(I) "Induction phase" means the phase of opioid treatment during which maintenance medication dosage levels are adjusted until a patient attains stabilization.

(J) "Stabilization phase" means the medical and psychosocial process of assisting the patient through acute intoxication and withdrawal management to the attainment of a medically stable, fully supported substance-free state, which may include the use of medications.

(K) "Withdrawal management" or "detoxification" is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. Detoxification denotes a clearing of toxins from the body of the patient who is acutely intoxicated and/or dependent on a substance of abuse. Withdrawal management seeks to minimize the physical harm caused by the intoxication and withdrawal of a substance of abuse. Withdrawal management occurs when the patient has a substance use disorder and either evidence of the characteristic withdrawal syndrome produced by withdrawal from that substance, or evidence that supports the expectation that such a syndrome would develop without the provision of detoxification services. Withdrawal management alone does not constitute substance abuse treatment or rehabilitation.

(L) "Ambulatory detoxification" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by trained practitioners authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of addiction, prevention of relapse of drug addiction, or both. Ambulatory detoxification is the provision of medically supervised evaluation, withdrawal management, and referral services without extended onsite monitoring. For purpose of rule 4730-4-02 of the Administrative Code, ambulatory detoxification does not include withdrawal management that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) In-patient treatment in a hospital, as defined in section 3727.01 of the Revised

Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addition services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body; or

(5) A youth services facility, as defined in section 103.75 of the Revised Code.

4730-4-02 **Standards and procedures for withdrawal management for substance use disorder.**

(A) In order to provide ambulatory withdrawal management, as that term is defined in rule 4730-4-01 of the Administrative Code, a physician assistant shall comply with the following requirements:

(1) The physician assistant shall hold a valid prescriber number;

(2) The physician assistant shall provide withdrawal management under the supervision of a physician who provides withdrawal management as part of the physician's normal course of practice and with whom the physician assistant has a supervision agreement;

(3) The physician assistant shall comply with all state and federal laws and rules applicable to prescribing; and

(4) The physician assistant who practices in a healthcare facility shall comply with all policies of the healthcare facility concerning the provision of withdrawal management.

(B) Prior to providing ambulatory withdrawal management for any substance use disorder the physician assistant shall inform the patient that ambulatory withdrawal management alone is not complete treatment for a substance use disorder. If the patient prefers continuing treatment for a substance use disorder, the physician assistant shall comply with the requirements of section 3719.064 of the Revised Code.

(C) The physician assistant shall provide accurate, objective and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(D) When providing withdrawal management for opioid use disorder a physician assistant may be authorized to use a medical device that is approved by the United States food and drug administration as an aid in the reduction of opioid withdrawal symptoms.

(E) Ambulatory withdrawal management for opioid use disorder.

(1) The physician assistant shall provide ambulatory withdrawal management only when the following conditions are met:

(a) The patient has adequate social, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management; and

(b) There is little risk of medication diversion.

(2) The physician assistant shall provide ambulatory withdrawal management under a defined set of policies and procedures or medical protocols, with patient placement in outpatient or residential settings consistent with American society of addiction medicine's level of care criteria. ~~I-WM or II-WM level of care, under which~~ Such services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a drug, and to effectively facilitate the patient's transition into treatment and recovery. In the event that ambulatory withdrawal management is unsafe or inappropriate for a patient, referral to a higher level of care, such as inpatient hospitalization shall be completed. The ASAM criteria can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours.

(3) Prior to providing ambulatory withdrawal management, the physician assistant shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history and physical examination sufficient to assure safety in commencing ambulatory withdrawal management and shall include a review of the patient's prescription history in OARRS. The assessment must focus on signs and symptoms associated with opioid use disorder and include assessment with a nationally recognized scale, such as one of the following:

(a) "Objective Opioid Withdrawal Scale" (OOWS);

(b) "Clinical Opioid Withdrawal Scale" (COWS); or

(c) "Subjective Opioid Withdrawal Scale" (SOWS).

(4) If any part of the assessment cannot be completed prior to the initiation of treatment, the physician assistant shall complete as soon as possible following initiation of treatment.

(5) The physician assistant shall inform the patient about the following before treatment for opioid withdrawal is initiated:

(a) The withdrawal management process and importance of subsequent treatment for substance use disorder, including information about all medications approved by the United States food and drug administration for use in MOUD treatment;

(b) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of MOUD treatment;

(c) The safe storage and disposal of prescribed medications.

(6) The physician assistant shall not establish standardized regimens of medications for management of substance withdrawal symptomatology but shall formulate

an individualized treatment plan based on the needs of the specific patient.

(7) For persons projected to be involved in withdrawal management for six months or less, the physician assistant shall offer the patient counseling as described in paragraph (D) of rule 4730-4-03 of the Administrative Code.

(8) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for use of licit and/or illicit drugs. The physician assistant shall consider revising the treatment plan or referring a patient who has a positive toxicological screening result to a higher level of care, and shall confer with the supervising physician prior to prescribing the buprenorphine/naloxone combination product to the patient.

(9) The physician assistant shall comply with the following requirements for the use of medication:

(a) The physician assistant may treat the patient's withdrawal symptoms with any of the following medications as determined to be most appropriate for the patient.

(i) A medication that is specifically FDA approved for the alleviation of withdrawal symptoms. Methadone may only be utilized with strict adherence to the stipulations of 21 C.F.R. 1306.07(b).

(ii) An alpha-2 adrenergic agent along with other non-narcotic medications as recommended in the American society of addiction medicine's "National Practice Guideline" (https://www.asam.org/), which is available from the medical board's website at https://med.ohio.gov;

(iii) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product), unless contraindicated, in which case buprenorphine mono-product may be utilized.

(b) The physician assistant shall not use anesthetic agents to treat the patient's withdrawal symptoms.

(c) The physician assistant shall comply with the following:

(i) Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

(ii) The physician assistant shall determine on an individualized basis the appropriate dosage of medication to ensure stabilization during withdrawal management.

(a) The dosage level shall be that which is effective in suppressing withdrawal symptoms and is well tolerated by the patient.

(b) The dosage level shall be consistent with the currently accepted standards of care.

(iii) In withdrawal management programs of thirty days or less duration, the physician assistant shall not prescribe nor dispense more than one week of unsupervised or take-home medications for the patient.

(10) The physician assistant shall offer the patient a prescription for an overdose reversal drug, directly provide them with the overdose reversal drug, or direct the patient to an easily accessible source to obtain the overdose reversal drug, such as http://www.naloxone.ohio.gov, a local health department, or other agency or facility that provides overdose reversal drugs.

(a) The physician assistant shall ensure that the patient, and if possible, those residing with the patient receives instruction on the drug's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(b) The physician assistant shall offer the patient a new prescription for an overdose reversal drug upon expiration or use.

(c) The physician assistant shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician assistant shall provide the patient with information on where to obtain the overdose reversal drug without a prescription.

(11) The physician assistant shall take steps to reduce the risk of medication diversion by doing one or more of the following: ~~using~~ frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

(F) The physician assistant who provides ambulatory withdrawal management for benzodiazepines or other sedatives shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/. (Search for "TIP 45") and available on the medical board's website at: https://med.ohio.gov.

(1) The physician assistant shall provide ambulatory withdrawal management for benzodiazepines with medication only when a patient has sufficient social, medical, and psychiatric stability when their use of benzodiazepines was primarily in therapeutic dose ranges and when they do not have polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical condition or severe psychiatric disorder, and no history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician assistant shall perform an assessment of the patient that focuses on signs and symptoms associated with benzodiazepine or other sedative use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Benzodiazepines" ("CIWA-B").

(3) Prior to providing ambulatory withdrawal management, the physician assistant shall conduct and document a biomedical and psychosocial evaluation of the patient to gather sufficient information and data to justify the use of this treatment intervention.

(4) The physician assistant shall instruct the patient about the following before treatment for benzodiazepine withdrawal management is initiated:

(a) Not to drive or operate dangerous machinery during treatment;.

(b) The withdrawal management process and importance of subsequent treatment for substance use disorder, including information about all medications approved by the United States food and drug administration for use in substance use disorder treatment;

(c) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of treatment for substance use disorder; and

(d) The safe storage and disposal of prescribed medications.

(5) During the ambulatory withdrawal management, the physician assistant shall regularly assess the patient so that medication dosage can be adjusted if needed.

(a) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for the use of licit and/or illicit drugs.

(b) The physician assistant shall consider revising the treatment plan or referring the patient who has a positive toxicology screening to a higher

level of care.

(c) The physician assistant shall take steps to reduce the chances of diversion by doing one or more of the following: ~~using~~ frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

(G) The physician assistant who provides ambulatory withdrawal management for withdrawal from alcohol addiction shall comply with paragraphs (A), (B), and (C) of this rule and "Clinical Practice Guideline on Alcohol Withdrawal Management by the American society of addiction medicine available from the American society of addiction medicine website at the following link:http://www.asam.org/quality-care/clinical-guidelines/alcohol-withdrawal-management-guideline.

(1) The physician assistant shall provide ambulatory withdrawal from alcohol ~~with medication management~~ only when:

(a) The patient has sufficient social, medical, and psychiatric stability to adhere to prescribed treatments and successfully complete withdrawal with minimal risk of complications;

(b) The patient is not at risk for serious withdrawal from substances other than alcohol; and

(c) The patient has ~~and when they do not have a polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal~~ symptoms, ~~have no comorbid medical conditions or severe psychiatric disorders, and~~ no history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician assistant shall perform an assessment of the patient. The assessment must focus on signs and symptoms associated with alcohol use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Alcohol-revised" ("CIWA-AR").

(3) Prior to providing ambulatory withdrawal management, the physician assistant shall perform a biomedical and psychosocial evaluation to gather sufficient information and data to justify the use of this treatment intervention.

(4) During the ambulatory withdrawal management, the physician assistant shall regularly assess the patient so that the dosage can be adjusted if needed:

(a) The physician assistant shall require the patient to undergo toxicological screenings in order to assess for the presence of alcohol metabolites, licit or illicit drugs;

(b) The physician assistant shall consider revising the treatment plan or referring a patient who has a positive toxicological screening test to a higher level of care; and

(c) The physician assistant shall take steps to reduce the risk of diversion by

doing one or more of the following: ~~using~~ frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

4730-4-02 **Standards and procedures for withdrawal management for drug or alcohol addiction.**

(A) In order to provide ambulatory detoxification, as that term is defined in rule 4730-4-01 of the Administrative Code, a physician assistant shall comply with all of the following requirements:

(1) The physician assistant shall hold a valid prescriber number.

(2) The physician assistant shall provide withdrawal management under the supervision of a physician who provides withdrawal management as part of the physician's normal course of practice and with whom the physician assistant has a supervision agreement.

(3) The physician assistant shall comply with all state and federal laws and rules applicable to prescribing, including holding a DATA 2000 waiver to prescribe buprenorphine if buprenorphine is to be prescribed for withdrawal management in a medical office, public sector clinic, or urgent care facility.

(4) The physician assistant who practices in a healthcare facility shall comply with all policies of the healthcare facility concerning the provision of withdrawal management.

(B) Prior to providing ambulatory detoxification, as that term is defined in rule 4730-4-01 of the Administrative Code, for any substance use disorder the physician assistant shall inform the patient that ambulatory detoxification alone is not substance abuse treatment. If the patient prefers substance abuse treatment, the physician assistant shall comply with the requirements of section 3719.064 of the Revised Code, by completing all of the following actions:

(1) Both orally and in writing, give the patient information about all drugs approved by the U.S. food and drug administration for use in medication-assisted treatment, including withdrawal management. That information was given shall be documented in the patient's medical record.

(2) If the patient agrees to enter opioid treatment and the physician assistant determines that such treatment is clinically appropriate, the physician assistant shall refer the patient to an opioid treatment program licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who provides treatment using Naltrexone or who holds the DATA 2000 waiver to provide office-based treatment for opioid use disorder. The name of the program, physician, physician assistant, or advanced practice registered nurse to whom the patient was referred, and the

date of the referral shall be documented in the patient record.

(C) When providing withdrawal management for opioid use disorder a physician assistant may be authorized to use a medical device that is approved by the United States food and drug administration as an aid in the reduction of opioid withdrawal symptoms.

(D) Ambulatory detoxification for opioid addiction.

(1) The physician assistant shall provide ambulatory detoxification only when all of the following conditions are met:

(a) A positive and helpful support network is available to the patient.

(b) The patient has a high likelihood of treatment adherence and retention in treatment.

(c) There is little risk of medication diversion.

(2) The physician assistant shall provide ambulatory detoxification under a defined set of policies and procedures or medical protocols consistent with American society of addiction medicine's level I-D or II-D level of care, under which services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a mood-altering drug, and to effectively facilitate the patient's transition into treatment and recovery. The ASAM criteria, third edition, can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours.

(3) Prior to providing ambulatory detoxification, the physician assistant shall perform an assessment of the patient. The assessment shall include a thorough medical history and physical examination. The assessment must focus on signs and symptoms associated with opioid addiction and include assessment with a nationally recognized scale, such as one of the following:

(a) "Objective Opioid Withdrawal Scale" (OOWS);

(b) "Clinical Opioid Withdrawal Scale" (COWS); or

(c) "Subjective Opioid Withdrawal Scale" (SOWS).

(4) Prior to providing ambulatory detoxification, the physician assistant shall conduct a biomedical and psychosocial evaluation of the patient, to include the following:

(a) A comprehensive medical and psychiatric history;

(b) A brief mental status exam;

(c) Substance abuse history;

(d) Family history and psychosocial supports;

(e) Appropriate physical examination;

(f) Urine drug screen or oral fluid drug testing;

(g) Pregnancy test for women of childbearing age and ability;

(h) Review of the patient's prescription information in OARRS;

(i) Testing for human immunodeficiency virus;

(j) Testing for hepatitis B;

(k) Testing for hepatitis C; and

(l) Consideration of screening for tuberculosis and sexually transmitted diseases in patients with known risk factors.

(m) For other than toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and pregnancy test, the physician assistant may satisfy the assessment requirements by reviewing records from a physical examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit. If any part of the assessment cannot be completed prior to the initiation of treatment, the physician assistant shall document the reason in the medical record.

(5) The physician assistant shall request and document review of an OARRS report on the patient.

(6) The physician assistant shall inform the patient about the following before the patient is undergoing withdrawal from opioids:

(a) The detoxification process and potential subsequent treatment for substance use disorder, including information about all drugs approved by the United States food and drug administration for use in medication-assisted treatment;

(b) The risk of relapse following detoxification without entry into medication-assisted treatment;

(c) The high risk of overdose and death when there is a relapse following detoxification;

(d) The safe storage and disposal of the medications.

(7) The physician assistant shall not establish standardized routines or schedules of increases or decreases of medications but shall formulate a treatment plan based on the needs of the specific patient.

(8) For persons projected to be involved in withdrawal management for six months or less, the physician assistant shall offer the patient counseling as described in paragraphs (F) and (G) of rule 4730-4-03 of the Administrative Code.

(9) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to demonstrate the absence of use of alternative licit and/or illicit drugs. The physician assistant shall consider referring a patient who has a positive urine/and or toxicological screening to a higher level of care, with such consideration documented in the patient's medical record, and shall confer with the supervising physician prior to prescribing the buprenorphine/naloxone combination product to the patient.

(10) The physician assistant shall comply with the following requirements for the use of medication:

(a) The physician assistant may treat the patient's withdrawal symptoms by use of any of the following drugs as determined to be most appropriate

for the patient.

(i) A drug, excluding methadone, that is specifically FDA approved for the alleviation of withdrawal symptoms

(ii) An alpha-2 adrenergic agent along with other non-narcotic medications as recommended in the American society of addiction medicine's "National Practice Guideline" (https://www.asam.org/), which is available from the medical board's website at https://med.ohio.gov;

(iii) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product). However, buprenorphine without naloxone (buprenorphine mono-product) may be used if a buprenorphine/naloxone combination product is contraindicated, with the contraindication documented in the patient record

(b) The physician assistant shall not use any of the following drugs to treat the patient's withdrawal symptoms:

(i) Methadone;

(ii) Anesthetic agents

(c) The physician assistant shall comply with the following:

(i) The physician assistant shall not initiate treatment with buprenorphine to manage withdrawal symptoms until between twelve and eighteen hours after the last dose of short-acting agonist such as heroin or oxycodone, and twenty-four to forty-eight hours after the last dose of long-acting agonist such as methadone. Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

(ii) The physician assistant shall determine on an individualized basis the appropriate dosage of medication to ensure stabilization

during withdrawal management.

(a) The dosage level shall be that which is well tolerated by the patient.

(b) The dosage level shall be consistent with the minimal standards of care.

(iii) In withdrawal management programs of thirty days or less duration, the physician assistant shall not allow more than one week of unsupervised or take-home medications for the patient.

(11) The physician assistant shall offer the patient a prescription for a naloxone kit.

(a) The physician assistant shall ensure that the patient receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(b) The physician assistant shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.

(c) The physician assistant shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician assistant shall provide the patient with information on where to obtain a kit without a prescription.

(12) The physician assistant shall take steps to reduce the chances of medication diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of OARRS.

(E) The physician assistant who provides ambulatory detoxification with medication management for withdrawal from benzodiazepines or other sedatives shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/. (Search for "TIP 45") and available on the medical board's website at: https://med.ohio.gov.

(1) The physician assistant shall provide ambulatory detoxification with medication management only when a positive and helpful support network is available to

the patient whose use of benzodiazepines was mainly in therapeutic ranges and who does not have polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical condition or severe psychiatric disorder, and no past history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory detoxification, the physician assistant shall perform and document an assessment of the patient that focuses on signs and symptoms associated with benzodiazepine or other sedative use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Benzodiazepines" ("CIWA-B").

(3) Prior to providing ambulatory detoxification, the physician assistant shall conduct and document a biomedical and psychosocial evaluation of the patient meeting the requirements of paragraph (B)(4) of this rule.

(4) The physician assistant shall instruct the patient not to drive or operate dangerous machinery during treatment.

(5) During the ambulatory detoxification, the physician assistant shall regularly assess the patient during the course of treatment so that dosage can be adjusted if needed.

(a) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to demonstrate the absence of use of alternative licit and/or illicit drugs.

(b) The physician assistant shall document consideration of referring the patient who has a positive urine and/or toxicology screening to a higher level of care.

(c) The physician assistant shall take steps to reduce the chances of diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of OARRS.

(F) The physician assistant who provides ambulatory detoxification with medication management of withdrawal from alcohol addiction shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/ (search for "TIP 45") and available from the medical board's website at:

https://med.ohio.gov.

(1) The physician assistant shall provide ambulatory detoxification from alcohol with medication management only when a positive and helpful support network is available to the patient who does not have a polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical conditions or severe psychiatric disorders, and no past history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory detoxification, the physician assistant shall perform and document an assessment of the patient. The assessment must focus on signs and symptoms associated with alcohol use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Alcohol-revised" ("CIWA-AR").

(3) Prior to providing ambulatory detoxification, the physician assistant shall perform and document a biomedical and psychosocial evaluation meeting the requirements of paragraph (D)(4) of this rule.

(4) During the course of ambulatory detoxification, the physician assistant shall assess the patient regularly:

(a) The physician assistant shall adjust the dosage as medically appropriate;

(b) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings in order to demonstrate the absence of illicit drugs;

(c) The physician assistant shall document the consideration of referring a patient who has a positive urine and/or toxicological screening to a higher level of care;

(5) If the patient agrees to enter alcohol treatment and the physician assistant determines that such treatment is clinically appropriate, the physician assistant shall refer the patient to an alcohol treatment program licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who provides treatment using any FDA approved forms of medication assisted treatment for alcohol use disorder. The name of the program, physician, physician assistant, or advanced practice registered nurse to whom the patient was referred, and the date of the referral shall be

documented in the patient record.

(6) The physician assistant shall instruct the patient not to drive or operate dangerous machinery during treatment.

4730-4-03 **Office-based opioid treatment.**

(A) A physician assistant who provides office-based opioid treatment("OBOT") shall comply with the following requirements:

(1) Before initiating OBOT, the physician assistant shall comply with section 3719.064 of the Revised Code.

(2) Comply with all federal and state laws and regulations governing the prescribing of the medication;

(3) Complete at least eight hours of "Category 1" continuing medical education relating to substance use disorder and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the continuing medical education requirement for biennial renewal of the physician assistant's license;

(4) Only provide OBOT if the provision of OBOT is within the supervising physician's normal course of practice and expertise;

(5) The physician assistant who provides OBOT shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history, examination, and laboratory testing. If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician assistant shall complete as soon as possible following initiation of treatment; and

(6) The physician assistant shall provide accurate, objective, and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(B) The physician assistant who provides OBOT shall establish a treatment plan that includes the following:

(1) The physician assistant's rationale for selection of the specific drug to be used in the treatment based upon discussion of all MOUDs and non-medication options with the patient;

(2) Patient education;

~~(3) The patient's written, informed consent;~~

(3) Random urine-drug screens;

(4) A signed treatment agreement that outlines the responsibilities of the patient and the physician assistant, and documents the patient's consent for treatment;

(5) Documentation regarding psychosocial intervention, pursuant to paragraph (D)

of this rule; and

(6) The treatment plan shall be revised if the patient does not show improvement with the original plan.

(C) The physician assistant shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

(1) TIP 63 "Medications for Opioid Use Disorder" (2021) available from the https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002.

(2) "ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update", available from the website of the American society of addiction medicine at: https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline.

(D) The physician assistant shall do the following with respect to psychosocial treatment for patients receiving OBOT:

(1) Assess for psychosocial treatment needs in addition to medication;

(2) Offer psychosocial interventions or referrals for psychosocial interventions to all patients, but OBOT should not be declined or discontinued if the patient is unable or unwilling to engage in psychosocial interventions;

(3) Ensure that psychosocial interventions are person-centered and tailored to the patient's insight, motivation, and stage of recovery;

(4) Focus the psychosocial interventions on retaining the patient in treatment, stabilizing the patient and assisting with progress in the patient's treatment and recovery;

(5) If the psychosocial interventions are not available or if the patient declines to participate, the physician assistant shall continue to treat the patient with OBOT provided that the patient adheres to all other treatment requirements;

(6) Psychosocial treatment or intervention includes the following:

(a) Cognitive behavioral treatment;

(b) Community reinforcement approach;

(c) Contingency management and motivational incentives;

(d) Motivational interviewing;

(e) Behavioral couples counseling;

(f) Twelve-step facilitation; and

(g) Other therapies based on the patient's individual needs;

(7) When necessary, the physician assistant may make referrals for psychosocial treatment to qualified behavioral healthcare providers, community addiction services or community mental health services providers as defined in rule 4730-4-01 of the Administrative Code; and

(8) The physician assistant may also refer patients for treatment with non-licensed paraprofessionals such as case managers and peer support specialists if the physician assistant determines such intervention would benefit the patient.

(E) The physician assistant who provides OBOT shall offer the patient a prescription for an overdose reversal drug, directly provide the patient with the overdose reversal drug, or direct the patient to an easily accessible source to obtain overdose reversal drugs, such as http://www.naloxone.ohio.gov, a local health department, or other agency or facility that provides overdose reversal drugs.

(1) The physician assistant shall ensure that the patient, and if possible, those residing with the patient, receives instruction on the overdose reversal drug's use including, but not limited to, recognizing the signs and symptoms of opioid overdose and calling 911 in an overdose situation.

(2) The physician assistant shall offer the patient a new prescription for an overdose reversal drug upon expiration or use.

(3) The physician assistant shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician assistant shall provide the patient with information on where to obtain overdose reversal drugs without a prescription.

(F) In addition to paragraphs (A) to (E) of this rule, the physician assistant who provides OBOT using buprenorphine products shall comply with the following requirements:

(1) Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www,accessdata.fda.gov/scripts/cder/rems/index.cfm. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician assistant who treats opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products

for use in OBOT.

(2) The physician assistant may prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations:

(a) When a patient is pregnant or breast-feeding;

(b) When converting a patient from buprenorphine mono-product to buprenorphine/naloxone combination product;

(c) In formulations other than tablet or film form for indications approved by the United States food and drug administration; or

(d) When the patient has a genuine allergy to or intolerance of a buprenorphine/naloxone combination product.

(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, gabapentin, or tramadol, the physician assistant shall only co-prescribe these substances when it is medically necessary.

(a) The physician assistant shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including whether acceptable alternative treatments are available and whether it is possible to lower the dose or discontinue the drug. If the physician assistant prescribing buprenorphine is the prescriber of the other drug, the physician assistant shall also consider these options and consider consultation for another healthcare provider. The physician assistant shall educate the patient about the serious risks of the combined use.

(b) The physician assistant shall document the rationale for discontinuing, lowering, or continuing the medication given potential risks and benefits.

(4) During the induction phase the physician assistant shall not prescribe a dosage that exceeds the recommendation in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the medical record. The physician assistant shall see the patient at least once a week during this phase.

(5) During the maintenance phase, the physician assistant shall prescribe a dosage of buprenorphine that avoids intoxication or sedation, prevents withdrawal, and suppresses significant drug craving. For the first twelve months of treatment, the physician assistant shall prescribe no more than a one-month supply of the buprenorphine product unless utilizing a formulation with duration of action exceeding one month, such as injections or implants.

~~(a) During the first ninety days of treatment, the physician assistant shall prescribe no more than a two-week supply of buprenorphine product.~~

~~unless utilizing a formulation with duration of action exceeding two weeks, such as injections or implants.~~

~~(b) Starting with the ninety first day of treatment and until the completion of twelve months of treatment, the physician assistant shall prescribe no more than a thirty-day supply of the buprenorphine product unless utilizing a formulation with duration of action exceeding thirty days, such as injections or implants.~~

(6) The physician assistant shall reduce the risk of buprenorphine diversion by using the lowest effective dose, and by using one or more of the following: scheduling appropriate frequency of office visits, conducting random pill counts, and checking OARRS and utilizing drug testing, serum medication levels, and oral fluid testing to assess for patient adherence to prescribed buprenorphine treatment.

(7) When using any sublingual formulation of buprenorphine, the physician assistant shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day, unless the physician assistant obtains a consultation from a addiction specialist physician recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine per day.

(8) The physician assistant shall incorporate relapse prevention strategies into the counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

(9) The physician assistant may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

(a) The physician assistant shall strictly comply with any required risk evaluation and mitigation strategy for the drug.

(b) The physician assistant shall prescribe an extended-release buprenorphine product strictly in accordance with the United States food and drug administration's approved labeling for the drug's use.

(c) The physician assistant shall document in the patient record the rationale for the use of the extended-release buprenorphine product.

(d) The physician assistant who orders or prescribes an extended release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care provider acting in accordance within the scope of their professional license.

unless utilizing a formulation with duration of action exceeding two weeks, such as injections or implants.

(b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician assistant shall prescribe no more than a thirty-day supply of the buprenorphine product unless utilizing a formulation with duration of action exceeding thirty days, such as injections or implants.

(6) The physician assistant shall reduce the risk of buprenorphine diversion by using the lowest effective dose, scheduling appropriate frequency of office visits, conducting random pill counts, and checking OARRS and utilizing drug testing, serum medication levels, and oral fluid testing to assess for patient adherence to prescribed buprenorphine treatment.

(7) When using any sublingual formulation of buprenorphine, the physician assistant shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day, unless the physician assistant obtains a consultation from a addiction specialist physician recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine per day.

(8) The physician assistant shall incorporate relapse prevention strategies into the counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

(9) The physician assistant may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

(a) The physician assistant shall strictly comply with any required risk evaluation and mitigation strategy for the drug.

(b) The physician assistant shall prescribe an extended-release buprenorphine product strictly in accordance with the United States food and drug administration's approved labeling for the drug's use.

(c) The physician assistant shall document in the patient record the rationale for the use of the extended-release buprenorphine product.

(d) The physician assistant who orders or prescribes an extended release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care provider acting in accordance within the scope of their professional license.

4730-4-03 **Office-based treatment for opioid addiction.**

(A) A physician assistant who provides OBOT shall comply with the following requirements:

(1) Before initiating OBOT, the physician assistant shall comply with section 3719.064 of the Revised Code.

(2) Comply with all federal and state laws and regulations governing the prescribing of the medication;

(3) Complete at least eight hours of "Category 1" continuing medical education relating to substance abuse and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the continuing medical education requirement for biennial renewal of the physician assistant's license; and

(4) Only provide OBOT if the provision of OBOT is within the supervising physician's normal course of practice and expertise.

(B) The physician assistant who provides OBOT shall perform and document an assessment of the patient.

(1) The assessment shall include all of the following:

(a) A comprenhensive medical and psychiatric history;

(b) A brief mental status exam;

(c) Substance abuse history;

(d) Family history and psychosocial supports;

(e) Appropriate physical examination;

(f) Urine drug screen or oral fluid drug testing;

(g) Pregnancy test for women of childbearing age and ability;

(h) Review of the patient's prescription information in OARRS;

(i) Testing for human immunodeficiency virus;

(j) Testing for hepatitis B;

(k) Testing for hepatitis C; and

(l) Consideration of screening for tuberculosis and sexually-transmitted diseases in patients with known risk factors.

(2) For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and the pregnancy test, the physician assistant may satisfy the assessment requirements by reviewing records from a physical examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit.

(3) If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician assistant shall document the reasons in the medical record.

(C) The physician assistant who provides OBOT shall establish and document a treatment plan that includes all of the following:

(1) The physician assistant's rationale for selection of the specific drug to be used in the medication-assisted treatment;

(2) Patient education;

(3) The patient's written, informed consent;

(4) Random urine-drug screens;

(5) A signed treatment agreement that outlines the responsibilities of the patient and the physician assistant; and

(6) A plan for psychosocial treatment, pursuant to paragraph (E) of this rule.

(D) The physician assistant shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

(1) SAMHSA treatment improvement protocol publications for medication assisted treatment available from the SAMHSA website at: https://store.samhsa.gov/.

(2) "National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," approved by the American society of addiction medicine in 2015, available from the website of the American society of addiction medicine at: https://www.asam.org/.

(E) The physician assistant shall refer and work jointly with a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as those terms are defined in rule 4730-4-01 of the Administrative Code, to determine the optimal type and intensity of psychosocial treatment for the patient and document the treatment plan in the patient record.

(1) The treatment shall, at a minimum, include a psychosocial needs assessment, supportive counseling, links to existing family supports, and referral to community services.

(2) The treatment shall include at least one of the following interventions, unless reasons for exception are documented in the patient record:

(a) Cognitive behavioral treatment;

(b) Community reinforcement approach;

(c) Contingency management/motivational incentives;

(d) Motivational interviewing; or

(e) Behavioral couples counseling.

(3) The treatment plan shall include a structure for revision of the treatment plan if the patient does not adhere to the original plan.

(4) When clinically appropriate or if the patient refuses treatment from a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as defined in rule 4730-4-01 of the Administrative Code, the physician assistant shall ensure that the OBOT treatment plan requires the patient to participate in a twelve step program. If the patient is required to participate in a twelve step program, the physician

assistant shall require the patient to provide documentation of on-going participation in the program.

(5) If the physician assistant refers the patient to a qualified behavioral healthcare provider, community addiction services provider, or community mental health servics provider, the physician assistant shall document the referral and the physician assistant's maintenance of meaningful interactions with the provider in the patient record.

(F) The physician assistant who provides OBOT shall offer the patient a prescription for a naloxone kit.

(1) The physician assistant shall ensure that the patient receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(2) The physician assistant shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.

(3) The physician assistant shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician assistant shall provide the patient with information on where to obtain a kit without a prescription.

(G) In addition to paragraphs (A) to (F) of this rule, the physician assistant who provides OBOT using buprenorphine products shall comply with all of the following requirements:

(1) The provision shall be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician assistant who treats opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products for use in OBOT.

(2) The physician assistant shall prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations, and shall fully document the evidence for the decision to use buprenorphine mono-product in the medical record:

(a) When a patient is pregnant or breast-feeding;

(b) When converting a patient from buprenorphine mono-product to buprenorphine/naloxone combination product;

(c) In formulations other than tablet or film form for indications approved by the United States food and drug administration;

(d) For withdrawal management when a buprenorphine/naloxone combination product is contraindicated, with the contraindication included in the patient record; or

(e) When the patient has an allergy to or intolerance of a buprenorphine/naloxone combination product, after explaining to the patient the difference between an allergic reaction and symptoms of opioid withdrawal precipitated by buprenorphine or naloxone, and with documentation included in the patient record.

(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, or tramadol, the physician assistant shall only co-prescribe these substances when it is medically necessary.

(a) The physician assistant shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including whether it is possible to taper the drug to discontinuation. If the physician assistant prescribing buprenorphine is the prescriber of the other drug, the physician assistant shall taper the other drug to discontinuation, if it is safe to do so. The physician assistant shall educate the patient about the serious risks of the combined use.

(b) The physician assistant shall document progress with achieving the tapering plan.

(4) During the induction phase the physician assistant shall not prescribe a dosage that exceeds the recommendation in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the medical record. The physician assistant shall see the patient at least once a week during this phase.

(5) During the stabilization phase, when using any oral formulation of buprenorphine, the physician assistant shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

(a) During the first ninety days of treatment, the physician assistant shall prescribe no more than a two-week supply of buprenorphine product containing naloxone.

(b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician assistant shall prescribe no more than a thirty-day supply of the buprenorphine product containing naloxone.

(6) The physician assistant shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of OARRS. The physician assistant shall also require urine drug screens, serum medication levels, or oral fluid drug testing at least twice per quarter for the first year of treatment and at least once per quarter thereafter.

(7) When using any oral formulation of buprenorphine, the physician assistant shall document in the medical record the rationale for prescribed doses exceeding sixteen milligrams of buprenorphine per day. The physician assistant shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day.

(8) The physician assistant shall incorporate relapse prevention strategies into the counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

(9) The physician assistant may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

(a) The physician assistant shall strictly comply with any required risk evaluation and mitigation strategy for the drug.

(b) The physician assistant shall prescribe an extended-release buprenorphine product strictly in accordance with the United States food and drug administration's approved labeling for the drug's use.

(c) The physician assistant shall document in the patient record the rationale for the use of the extended-release buprenorphine product.

(d) The physician assistant who orders or prescribes an extended release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care provider acting in accordance with the scope of their professional license.

4730-4-04 **Medication-assisted treatment using naltrexone.**

(A) In addition to the requirements in paragraphs (A) to (E) of rule 4730-4-03 of the Administrative Code, the physician assistant using naltrexone to treat opioid use disorder shall comply with the following requirements:

(1) Before initiating naltrexone, the physician assistant shall take measures to ensure that the patient is opioid abstinent for an adequate period of time after completing opioid withdrawal to avoid precipitated withdrawal. The physician assistant shall alert the patient of the risk of potentially lethal opioid overdose if they stop naltrexone and use opioids.

(2) The physician assistant shall use oral naltrexone only for treatment of patients who are highly motivated.

(a) The dosage regime shall strictly comply with the United States food and drug administration approved labeling for naltrexone hydrochloride tablets.

(b) The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.

(c) The physician assistant shall ~~conduct random pill counts and~~ require urine drug screens, serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

(d) The physician assistant shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

(B) The physician assistant may treat a patient with extended-release naltrexone for opioid or alcohol dependence or for co-occurring opioid and alcohol use disorders.

(1) The physician assistant should consider treatment with extended-release naltrexone for patients who have difficulties with treatment adherence.

(2) The dosage shall strictly comply with the United States food and drug administration approved labeling for extended-release naltrexone.

(3) The physician assistant shall determine the effectiveness of treatment with extended-release naltrexone by utilizing drug testing, serum medication levels, and oral fluid testing throughout the course of treatment.

(4) The physician assistant shall incorporate relapse prevention strategies into

counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

4730-4-04 **Medication-assisted treatment using naltrexone.**

(A) In addition to the requirements in paragraphs (A) to (F) of rule 4730-4-03 of the Administrative Code, the physician assistant using naltrexone to treat opioid use disorder shall comply with all of the following requirements:

(1) Prior to treating a patient with naltrexone, the physician assistant shall inform the patient about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids. The physician assistant shall take measures to ensure that the patient is adequately detoxified from opioids and is no longer physically dependent prior to treatment with naltrexone.

(2) The physician assistant shall use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated.

(a) The dosage regime shall strictly comply with the United States food and drug administration approved labeling for naltrexone hydrochloride tablets.

(b) The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.

(c) The physician assistant shall require urine drug screens, serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

(d) The physician assistant shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

(B) The physician assistant may treat a patient with extended-release naltrexone for opioid dependence or for co-occurring opioid and alcohol use disorders.

(1) The physician assistant should consider treatment with extended-release naltrexone for patients who have issues with treatment adherence.

(2) The injection dosage shall strictly comply with the United States food and drug administration approved labeling for extended-release naltrexone.

(3) The physician assistant shall incorporate relapse prevention strategies into

counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

4731-33-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means pharmacotherapy in a private office or public sector clinic that is not otherwise regulated by practitioners authorized to prescribe outpatient supplies of medications approved by the United States food and drug administration for the treatment of opioid use disorder. OBOT includes treatment with all controlled substance medications approved by the United States food and drug administration for such treatment. OBOT does not include treatment that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) A hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addiction services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body;

(5) A youth services facility, as defined in section 103.75 of the Revised Code; and

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

(B) "SAMHSA" means the United States substance abuse and mental health services administration.

(C) “Addiction specialist physician” means a physician who holds one of the following medical subspecialty certifications:

(1) Subspecialty board certification in addiction medicine by the American board of preventative medicine (“ABPM”);

(2) Subspecialty board certification in addiction psychiatry by the American board of psychiatry and neurology (“ABPN”);

(3) Subspecialty board certification in addiction medicine by the American osteopathic association (“AOA”); or

(4) Certification by the American board of addiction medicine (“ABAM”)

(D) “Medications for Opioid Use Disorder” or “MOUD” refers to all medications approved by the United States food and drug administration for the treatment of opioid use disorder.

(E) "Substance use disorder" indicates a problematic pattern of substance use leading to clinically significant impairment or distress as determined by application of the diagnostic criteria in the "Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition-Text Revision" or "DSM-5-TR."

(F) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(G) For purposes of the rules in this chapter:

(1) "Qualified behavioral healthcare provider" means the following healthcare providers practicing within the scope of the professional license:

(a) Addiction medicine specialist physician, or board-certified psychiatrist, licensed under Chapter 4731 of the Revised Code;

(b) Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732 of the Revised Code;

(c) Licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, licensed chemical dependency counselor II, or licensed chemical dependency counselor assistant licensed under Chapter 4758 of the Revised Code;

(d) Professional clinical counselor, licensed professional counselor, licensed independent social worker, licensed social worker, or marriage and family therapist, licensed under Chapter 4757 of the Revised Code;

(e) Advanced practice registered nurse, licensed as a clinical nurse specialist under Chapter 4723 of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center.

(f) Advanced practice registered nurse, licensed as a nurse practitioner under Chapter 4723 of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center; and

(g) An advanced practice registered nurse, licensed under Chapter 4723 of the Revised Code, who holds subspecialty certification as a certified addiction registered nurse-advanced practice issued by the addictions nursing certification board.

(2) Nothing in this paragraph shall be construed to prohibit a physician assistant licensed under Chapter 4730 of the Revised Code who practices under a

supervision agreement with a board-certified addiction psychiatrist, board certified addiction medicine specialist, or psychiatrist who is licensed as a physician under Chapter 4731 of the Revised Code, from providing services within the normal course of practice and expertise of the supervising physician, including addiction services, other mental health services, and physician delegated prescriptive services in compliance with Ohio and federal laws and rules.

(H) "Community addiction services provider," has the same meaning as in section 5119.01 of the Revised Code.

(I) "Community mental health services provider," has the same meaning as in section 5119.01 of the Revised Code.

(J) "Induction phase," means the phase of MOUD during which the patient is started on an FDA-approved medication for substance use disorder treatment.

(K) “Stabilization phase” means the period of time following the induction phase, when medication doses are adjusted to target a reduction in substance use disorder symptoms.

(L) “Maintenance phase," means the ongoing period of time when the patient’s medication dose reaches a therapeutic level, allowing the patient to focus on other recovery activities.

(M) "Withdrawal management" is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. Withdrawal management occurs when the patient has a substance use disorder and either evidence of the characteristic withdrawal syndrome produced by withdrawal from that substance or evidence that supports the expectation that such a syndrome would develop without the provision of medical withdrawal management services. Withdrawal management alone does not constitute completed substance use disorder treatment or rehabilitation.

(N) "Ambulatory withdrawal management" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by a physician authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of substance use disorder. Ambulatory withdrawal management is the provision of medically supervised evaluation, treatment, and referral services without extended onsite monitoring. For the purpose of rule 4731-33-02 of the Administrative Code, ambulatory withdrawal management does not include withdrawal management that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) In-patient treatment in a hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addition services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body;

(5) A youth services facility, as defined in section 103.75 of the Revised Code; and

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

4731-33-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means medication-assisted treatment, as that term is defined in this rule, in a private office or public sector clinic that is not otherwise regulated, by practitioners authorized to prescribe outpatient supplies of medications approved by the United States food and drug administration for the treatment of opioid addiction or dependence, prevention of relapse of opioid addiction or dependence, or both. OBOT includes treatment with all controlled substance medications approved by the United States food and drug administration for such treatment. OBOT does not include treatment that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) A hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addiction services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body; or

(5) A youth services facility, as defined in section 103.75 of the Revised Code.

(B) "SAMHSA" means the United States substance abuse and mental health services administration.

(C) "Medication-assisted treatment" means alcohol or drug addiction services that are accompanied by medication that has been approved by the United States food and drug administration for the treatment of substance use disorder, prevention of relapse of substance use disorder, or both.

(D) "Substance use disorder" includes misuse, dependence, and addiction to alcohol and/or legal or illegal drugs, as determined by diagnostic criteria in the "Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition" or "DSM-5."

(E) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(F) For purposes of the rules in Chapter 4731-33 of the Administrative Code:

(1) "Qualified behavioral healthcare provider" means the following who is practicing within the scope of the professional license:

(a) Board certified addictionologist, board certified addiction psychiatrist, or psychiatrist, licensed under Chapter 4731. of the Revised Code;

(b) Licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, licensed chemical dependency counselor II, or licensed chemical dependency counselor assistant licensed under Chapter 4758. of the Revised Code;

(c) Professional clinical counselor, licensed professional counselor, licensed independent social worker, licensed social worker, or marriage and family therapist, licensed under Chapter 4757. of the Revised Code;

(d) Advanced practice registered nurse, licensed as a clinical nurse specialist under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center.

(e) Advanced practice registered nurse, licensed as a nurse practitioner under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center;

(f) Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732. of the Revised Code; or

(g) An advanced practice registered nurse, licensed under Chapter 4723. of the Revised Code, who holds subspecialty certification as a certified addiction registered nurse-advanced practice issued by the addictions nursing certification board.

(2) Nothing in this paragraph shall be construed to prohibit a physician assistant licensed under Chapter 4730. of the Revised Code who practices under a supervision agreement with a board certified addiction psychiatrist, board certified addictionologist, or psychiatrist who is licensed as a physician under Chapter 4731. of the Revised Code, from providing services within the normal course of practice and expertise of the supervising physician, including addiction services, other mental health services, and physician delegated prescriptive services in compliance with Ohio and federal laws and

rules.

(G) "Community addiction services provider," has the same meaning as in section 5119.01 of the Revised Code.

(H) "Community mental health services provider," has the same meaning as in section 5119.01 of the Revised Code.

(I) "Induction phase," means the phase of opioid treatment during which maintenance medication dosage levels are adjusted until a patient attains stabilization.

(J) "Stabilization phase," means the medical and psychosocial process of assisting the patient through acute intoxication and withdrawal management to the attainment of a medically stable, fully supported substance-free state, which may include the use of medications.

(K) "Withdrawal management" or "detoxification" is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. Detoxification denotes a clearing of toxins from the body of the patient who is acutely intoxicated and/or dependent on a substance of abuse. Withdrawal management seeks to minimize the physical harm caused by the intoxication and withdrawal of a substance of abuse. Withdrawal management or detoxification occurs when the patient has a substance use disorder and either evidence of the characteristic withdrawal syndrome produced by withdrawal from that substance or evidence that supports the expectation that such a syndrome would develop without the provision of detoxification services. Withdrawal management alone does not constitute substance abuse treatment or rehabilitation.

(L) "Ambulatory detoxification" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by a physician authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of addiction, prevention of relapse of addiction, or both. Ambulatory detoxification is the provision of medically supervised evaluation, withdrawal management, and referral services without extended onsite monitoring. For the purpose of rule 4731-33-02 of the Administrative Code, ambulatory detoxification does not include withdrawal management that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) In-patient treatment in a hospital, as defined in section 3727.01 of the Revised

Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addition services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body; or

(5) A youth services facility, as defined in section 103.75 of the Revised Code.

4731-33-02 **Standards and procedures for withdrawal management for substance use disorder.**

(A) A physician who provides withdrawal management, as that term is defined in rule 4731-33-01 of the Administrative Code, shall comply with all federal and state laws and rules applicable to prescribing.

(B) Prior to providing ambulatory withdrawal management for any substance use disorder the physician shall inform the patient that ambulatory withdrawal management alone is not complete treatment for a substance use disorder. If the patient prefers continuing treatment for a substance use disorder, the physician shall comply with the requirements of section 3719.064 of the Revised Code.

(C) The physician shall provide accurate, objective and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(D) When providing withdrawal management for opioid use disorder the physician may use a medical device that is approved by the United States food and drug administration as an aid in the reduction of opioid withdrawal symptoms.

(E) Ambulatory withdrawal management for opioid use disorder.

(1) The physician shall provide ambulatory withdrawal management only when the following conditions are met:

(a) The patient has adequate social, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management.; and

(b) There is little risk of medication diversion.

(2) The physician shall provide ambulatory withdrawal management under a defined set of policies and procedures or medical protocols, with patient placement in outpatient or residential settings consistent with American society of addiction medicine's level of care criteria. ~~I-WM or II-WM level of care, under which~~ Such services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a drug, and to effectively facilitate the patient's transition into treatment and recovery. In the event that ambulatory withdrawal management is unsafe or inappropriate for a patient, referral to a higher level of care, such as inpatient hospitalization shall be completed. The ASAM criteria can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours.

(3) Prior to providing ambulatory withdrawal management, the physician shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history and physical examination sufficient to assure safety in commencing ambulatory withdrawal management and shall include

a review of the patient's prescription history in OARRS. The assessment must focus on signs and symptoms associated with opioid use disorder and include assessment with a nationally recognized scale, such as one of the following:

(a) "Objective Opioid Withdrawal Scale" (OOWS);

(b) "Clinical Opioid Withdrawal Scale" (COWS); or

(c) "Subjective Opioid Withdrawal Scale" (SOWS).

(4) If any part of the assessment cannot be completed prior to the initiation of treatment, the physician complete as soon as possible following initiation of treatment.

(5) The physician shall inform the patient about the following before treatment for opioid withdrawal is initiated:

(a) The withdrawal management process and importance of subsequent treatment for substance use disorder, including information about all medications approved by the United States food and drug administration for use in MOUD treatment;

(b) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of MOUD treatment;

(c) The safe storage and disposal of prescribed medications.

(6) The physician shall not establish standardized regimens of medications for management of substance withdrawal symptomatology but shall formulate an individualized treatment plan based on the needs of the specific patient.

(7) For persons projected to be involved in withdrawal management for six months or less, the physician shall offer the patient counseling as described in paragraph (D) of rule 4731-33-03 of the Administrative Code.

(8) The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for use of licit and/or illicit drugs. The physician shall consider revising the treatment plan or referring a patient who has a positive toxicological screening result to a higher level of care.

(9) The physician shall comply with the following requirements for the use of medication:

(a) The physician may treat the patient's withdrawal symptoms with any of the following medications as determined to be most appropriate for the patient.

(i) A medication that is specifically FDA approved for the alleviation of withdrawal symptoms. Methadone may only be utilized with strict adherence to the stipulations of 21 C.F.R. 1306.07(b).

(ii) An alpha-2 adrenergic agent along with other non-narcotic medications as recommended in the American Society of Addiction Medicine's National Practice Guideline (https://www.asam.org/), which is available on the Medical Board's website at: https://www.med.ohio.gov;

(iii) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product), unless contraindicated, in which case buprenorphine mono-product may be utilized.

(b) The physician shall not use anesthetic agents to treat the patient's withdrawal symptoms:

(c) The physician shall comply with the following:

(i) Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

(ii) The physician shall determine on an individualized basis the appropriate dosage of medication to ensure stabilization during withdrawal management.

(a) The dosage level shall be that which is effective in suppressing withdrawal symptoms and is well tolerated by the patient.

(b) The dosage level shall be consistent with the currently accepted standards of care.

(iii) In withdrawal management programs of thirty days or less duration, the physician shall not prescribe nor dispense more than one week of unsupervised or take-home medications for the patient.

(10) The physician shall offer the patient a prescription for an overdose reversal drug, directly provide them with the overdose reversal drug, or direct the patient to an easily accessible source to obtain the overdose reversal drug,

such as http://www.naloxone.ohio.gov, a local health department, or other agency or facility that provides overdose reversal drugs.

(a) The physician shall ensure that the patient, and if possible, those residing with the patient receives instruction on the drug's use including, but not limited to, recognizing the signs and symptoms of opioid overdose and calling 911 in an overdose situation.

(b) The physician shall offer the patient a new prescription for an overdose reversal drug upon expiration or use.

(c) The physician shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician shall provide the patient with information on where to obtain the overdose reversal drug without a prescription.

(11) The physician shall take steps to reduce the risk of medication diversion by doing one or more of the following: ~~using~~ frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

(F) The physician who provides ambulatory withdrawal management for benzodiazepines or other sedatives shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/ (search for "TIP 45") and available on the medical board's website at: https://med.ohio.gov.

(1) The physician shall provide ambulatory withdrawal management for benzodiazepines with medication only when a patient has sufficient social, medical, and psychiatric stability when their use of benzodiazepines was primarily in therapeutic dose ranges and when they do not have polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical condition or severe psychiatric disorder, and no history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician shall perform an assessment of the patient that focuses on signs and symptoms associated with benzodiazepine or other sedative use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Benzodiazepines" ("CIWA-B").

(3) Prior to providing ambulatory withdrawal management, the physician shall conduct a biomedical and psychosocial evaluation of the patient to gather sufficient information and data to justify the use of this treatment intervention.

(4) The physician shall instruct the patient about the following before treatment for benzodiazepine withdrawal management is initiated:

(a) Not to drive or operate dangerous machinery during treatment.;

(b) The withdrawal management process and importance of subsequent treatment for substance use disorder, including information about all medications approved by the United States food and drug administration for use in substance use disorder treatment;

(c) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of treatment for substance use disorder; and

(d) The safe storage and disposal of prescribed medications.

(5) During the ambulatory withdrawal management, the physician shall regularly assess the patient so that medication dosage can be adjusted if needed.

(a) The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for the use of licit and/or illicit drugs.

(b) The physician shall consider revising the treatment plan or referring the patient who has a positive toxicology screening to a higher level of care.

(c) The physician shall take steps to reduce the risk of diversion by doing one or more of the following: ~~using~~ frequent office visits, pill counts, urine drug screening and frequent checks of OARRS.

(G) The physician who provides ambulatory withdrawal management for withdrawal from alcohol shall comply with paragraphs (A), (B), and (C) of this rule and "Clinical Practice Guideline on Alcohol Withdrawal Management by the American society of addiction medicine available from the American society of addiction medicine website at the following link: https://www.asam.org/quality-care/clinical -guidelines/alcohol- withdrawal-management-guideline.

(1) The physician shall provide ambulatory withdrawal from alcohol ~~with medication management~~ only when:

(a) The patient has sufficient social, medical, and psychiatric stability to adhere to prescribed treatments and successfully complete withdrawal with minimal risk of complications;

(b) The patient is not at risk for serious withdrawal from substances other than alcohol; and

(c) The patient has ~~and when they do not have a polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical conditions or severe~~

~~psychiatric disorders, and~~ no history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician shall perform an assessment of the patient. The assessment must focus on signs and symptoms associated with alcohol use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Alcohol-revised" ("CIWA-AR").

(3) Prior to providing ambulatory withdrawal management, the physician shall perform a biomedical and psychosocial evaluation to gather sufficient information and data to justify the use of this treatment intervention.

(4) During the ambulatory withdrawal management, the physician shall regularly assess the patient so that the dosage can be adjusted if needed.

(a) The physician shall require the patient to undergo toxicological screenings in order to assess for the presence of alcohol metabolites, licit or illicit drugs;

(b) The physician shall consider revising the treatment plan or referring a patient who has a positive toxicological screening test to a higher level of care; and

(c) The physician shall take steps to reduce the risk of diversion by doing one or more of the following: ~~using~~ frequent office visits, pill counts, urine drug screening and frequent checks of OARRS.

4731-33-02 **Standards and procedures for withdrawal management for drug or alcohol addiction.**

(A) A physician who provides withdrawal management, as that term is defined in rule 4731-33-01 of the Administrative Code, shall comply with all federal and state laws and rules applicable to prescribing, including holding a "DATA 2000" waiver to prescribe buprenorphine if buprenorphine is to be prescribed for withdrawal management in a medical office, public sector clinic, or urgent care facility.

(B) Prior to providing ambulatory detoxification, as that term is defined in rule 4731-33-01 of the Administrative Code, for any substance use disorder the physician shall inform the patient that ambulatory detoxification alone is not substance abuse treatment. If the patient prefers substance abuse treatment, the physician shall comply with the requirements of section 3719.064 of the Revised Code, by completing all of the following actions:

(1) Both orally and in writing, give the patient information about all drugs approved by the U.S. food and drug administration for use in medication-assisted treatment, including withdrawal management. That information was given shall be documented in the patient's medical record.

(2) If the patient agrees to enter opioid treatment and the physician determines that such treatment is clinically appropriate, the physician shall refer the patient to an opioid treatment program licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who provides treatment using Naltrexone or who holds the DATA 2000 waiver to provide office-based treatment for opioid use disorder. The name of the program, physician, physician assistant, or advanced practice registered nurse to whom the patient was referred, and the date of the referral shall be documented in the patient record.

(C) When providing withdrawal management for opioid use disorder the physician may use a medical device that is approved by the United States food and drug administration as an aid in the reduction of opioid withdrawal symptoms.

(D) Ambulatory detoxification for opioid addiction.

(1) The physician shall provide ambulatory detoxification only when all of the following conditions are met:

(a) A positive and helpful support network is available to the patient.

(b) The patient has a high likelihood of treatment adherence and retention in treatment.

(c) There is little risk of medication diversion.

(2) The physician shall provide ambulatory detoxification under a defined set of policies and procedures or medical protocols consistent with American society of addiction medicine's level I-D or II-D level of care, under which services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a mood-altering drug, and to effectively facilitate the patient's transition into treatment and recovery. The ASAM criteria, third edition, can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours.

(3) Prior to providing ambulatory detoxification, the physician shall perform an assessment of the patient. The assessment shall include a thorough medical history and physical examination. The assessment must focus on signs and symptoms associated with opioid addiction and include assessment with a nationally recognized scale, such as one of the following:

(a) "Objective Opioid Withdrawal Scale" (OOWS);

(b) "Clinical Opioid Withdrawal Scale" (COWS); or

(c) "Subjective Opioid Withdrawal Scale" (SOWS).

(4) Prior to providing ambulatory detoxification, the physician shall conduct a biomedical and psychosocial evaluation of the patient, to include the following:

(a) A comprehensive medical and psychiatric history;

(b) A brief mental status exam;

(c) Substance abuse history;

(d) Family history and psychosocial supports;

(e) Appropriate physical examination;

(f) Urine drug screen or oral fluid drug testing;

(g) Pregnancy test for women of childbearing age and ability;

(h) Review of the patient's prescription information in OARRS;

(i) Testing for human immunodeficiency virus;

(j) Testing for hepatitis B;

(k) Testing for hepatitis C; and

(l) Consideration of screening for tuberculosis and sexually-transmitted diseases in patients with known risk factors.

(m) For other than toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and pregnancy test, the physician may satisfy the assessment requirements by reviewing records from a physical examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit. If any part of the assessment cannot be completed prior to the initiation of treatment, the physician shall document the reason in the medical record.

(5) The physician shall request and document review of an OARRS report on the patient.

(6) The physician shall inform the patient about the following before the patient is undergoing withdrawal from opioids:

(a) The detoxification process and potential subsequent treatment for substance use disorder, including information about all drugs approved by the United States food and drug administration for use in medication-assisted treatment;

(b) The risk of relapse following detoxification without entry into medication-assisted treatment;

(c) The high risk of overdose and death when there is a relapse following

detoxification;

(d) The safe storage and disposal of the medications.

(7) The physician shall not establish standardized routines or schedules of increases or decreases of medications but shall formulate a treatment plan based on the needs of the specific patient.

(8) For persons projected to be involved in withdrawal management for six months or less, the physician shall offer the patient counseling as described in paragraphs (F) and (G) of rule 4731-33-03 of the Administrative Code.

(9) The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to demonstrate the absence of use of alternative licit and/or illicit drugs. The physician shall consider referring a patient who has a positive urine/and or toxicological screening to a higher level of care, with such consideration documented in the patient's medical record.

(10) The physician shall comply with the following requirements for the use of medication:

(a) The physician may treat the patient's withdrawal symptoms by use of any of the following drugs as determined to be most appropriate for the patient.

(i) A drug, excluding methadone, that is specifically FDA approved for the alleviation of withdrawal symptoms.

(ii) An alpha-2 adrenergic agent along with other non-narcotic medications as recommended in the American Society of Addiction Medicine’s National Practice Guideline (https://www.asam.org/), which is available on the Medical Board’s website at: https://www.med.ohio.gov;

(iii) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product). However, buprenorphine without naloxone (buprenorphine mono-product) may be used if a buprenorphine/naloxone combination product is contraindicated, with the contraindication documented in the patient record.

(b) The physician shall not use any of the following drugs to treat the patient’s withdrawal symptoms:

(i) Methadone;

(ii) Anesthetic agents

(c) The physician shall comply with the following:

(i) The physician shall not initiate treatment with buprenorphine to manage withdrawal symptoms until between twelve and eighteen hours after the last dose of short-acting agonist such as heroin or oxycodone, and twenty-four to forty-eight hours after the last dose of long-acting agonist such as methadone. Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

(ii) The physician shall determine on an individualized basis the appropriate dosage of medication to ensure stabilization during withdrawal management.

(a) The dosage level shall be that which is well tolerated by the patient.

(b) The dosage level shall be consistent with the minimal standards of care.

(iii) In withdrawal management programs of thirty days or less duration, the physician shall not allow more than one week of unsupervised or take-home medications for the patient.

(11) The physician shall offer the patient a prescription for a naloxone kit.

(a) The physician shall ensure that the patient receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(b) The physician shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.

(c) The physician shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician shall provide the patient with information on where to obtain a kit without a prescription.

(12) The physician shall take steps to reduce the chances of medication diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of OARRS.

(E) The physician who provides ambulatory detoxification with medication management for withdrawal from benzodiazepines or other sedatives shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/ (search for "TIP 45") and available on the medical board’s website at: https://med.ohio.gov.

(1) The physician shall provide ambulatory detoxification with medication management only when a positive and helpful support network is available to the patient whose use of benzodiazepines was mainly in therapeutic ranges and who does not have polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical condition or severe psychiatric disorder, and no past history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory detoxification, the physician shall perform and document an assessment of the patient that focuses on signs and symptoms associated with benzodiazepine or other sedative use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Benzodiazepines" ("CIWA-B").

(3) Prior to providing ambulatory detoxification, the physician shall conduct and document a biomedical and psychosocial evaluation of the patient meeting the requirements of paragraph (B)(4) of this rule.

(4) The physician shall instruct the patient not to drive or operate dangerous machinery during treatment.

(5) During the ambulatory detoxification, the physician shall regularly assess the patient during the course of treatment so that dosage can be adjusted if needed.

(a) The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to demonstrate the absence of use of alternative licit and/or illicit drugs.

(b) The physician shall document consideration of referring the patient who has a positive urine and/or toxicology screening to a higher level of care.

(c) The physician shall take steps to reduce the chances of diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of OARRS.

(F) The physician who provides ambulatory detoxification with medication management of withdrawal from alcohol addiction shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/ (search for "TIP 45") and available on the medical board's website at: https://med.ohio.gov.

(1) The physician shall provide ambulatory detoxification from alcohol with medication management only when a positive and helpful support network is available to the patient who does not have a polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical conditions or severe psychiatric disorders, and no past history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory detoxification, the physician shall perform and document an assessment of the patient. The assessment must focus on signs and symptoms associated with alcohol use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Alcohol-revised" ("CIWA-AR").

(3) Prior to providing ambulatory detoxification, the physician shall perform and document a biomedical and psychosocial evaluation meeting the requirements of paragraph (D)(4) of this rule.

(4) During the course of ambulatory detoxification, the physician shall assess the

patient regularly:

(a) The physician shall adjust the dosage as medically appropriate;

(b) The physician shall require the patient to undergo urine and/or other toxicological screenings in order to demonstrate the absence of illicit drugs;

(c) The physician shall document the consideration of referring a patient who has a positive urine and/or toxicological screening to a higher level of care;

(5) If the patient agrees to enter alcohol treatment and the physician determines that such treatment is clinically appropriate, the physician shall refer the patient to an alcohol treatment program licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who provides treatment using any FDA approved forms of medication assisted treatment for alcohol use disorder. The name of the program, physician, physician assistant, or advanced practice registered nurse to whom the patient was referred, and the date of the referral shall be documented in the patient record.

(6) The physician shall instruct the patient not to drive or operate dangerous machinery during treatment.

4731-33-03 **Office-based opioid treatment.**

(A) A physician who provides office-based opioid treatment ("OBOT") shall comply with the following requirements:

(1) Before initiating OBOT, the physician shall comply with section 3719.064 of the Revised Code;

(2) Comply with all federal and state laws and regulations governing the prescribing of the medication;

(3) Complete at least eight hours of "Category 1" continuing medical education relating to substance use disorder and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the physician's "Category 1" continuing medical education requirement for biennial renewal of the physician's license;

(4) The physician who provides OBOT shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history, examination and laboratory testing. If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician shall complete as soon as possible following initiation of treatment; and

(5) The physician shall provide accurate, objective and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(B) The physician who provides OBOT shall establish a treatment plan that includes the following:

(1) The physician's rationale for selection of the specific drug to be used in the treatment based upon discussion of all MOUDs and non-medication options with the patient;

(2) Patient education;

~~(3) The patient's written, informed consent;~~

(3) Random urine-drug screens;

(4) A signed treatment agreement that outlines the responsibilities of the patient and the physician, and documents the patient's consent for treatment;

(5) Documentation regarding psychosocial interventions, pursuant to paragraph (D) of this rule; and

(6) The treatment plan shall be revised if the patient does not show improvement

with the original plan.

(C) The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

(1) TIP 63 “Medications for Opioid Use Disorder” (2021) available from the https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002.

(2) “ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update," available from the website of the American society of addiction medicine at https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline.

(D) The physician shall do the following with respect to psychosocial treatment for patients receiving OBOT:

(1) Assess for psychosocial treatment needs in addition to medication;

(2) Offer psychosocial interventions or referrals for psychosocial interventions to all patients, but OBOT should not be declined or discontinued if the patient is unable or unwilling to engage in psychosocial interventions;.

(3) Ensure that psychosocial interventions are person-centered and tailored to the patient’s insight, motivation, and stage of recovery;

(4) Focus the psychosocial interventions on retaining the patient in treatment, stabilizing the patient and assisting with progress in the patient’s treatment and recovery;

(5) If the psychosocial interventions are not available or if the patient declines to participate, the physician shall continue to treat the patient with OBOT provided that the patient adheres to all other treatment requirements;

(6) Psychosocial treatment or intervention includes the following:

(a) Cognitive behavioral treatment;

(b) Community reinforcement approach;

(c) Contingency management and motivational incentives;

(d) Motivational interviewing;

(e) Behavioral couples counseling;

(f) Twelve-step facilitation; and

(g) Other therapies based on the patient's individual needs;

(7) When necessary, the physician may make referrals for psychosocial treatment to qualified behavioral healthcare providers, community addiction services or community mental health services providers as defined in rule 4731-33-01 of the Administrative Code; and

(8) The physician may also refer patients for treatment with non-licensed paraprofessionals such as case managers and peer support specialists if the physician determines such intervention would benefit the patient.

(E) The physician who provides OBOT shall offer the patient a prescription for an overdose reversal drug, directly provide the patient with the overdose reversal drug, or direct the patient to an easily accessible source to obtain overdose reversal drugs, such as http://www.naloxone.ohio.gov, a local health department, or other agency or facility that provides overdose reversal drugs.

(1) The physician shall ensure that the patient, and if possible, those residing with the patient, receives instruction on the overdose reversal drug's use including, but not limited to, recognizing the signs and symptoms of opioid overdose and calling 911 in an overdose situation.

(2) The physician shall offer the patient a new prescription for an overdose reversal drug upon expiration or use.

(3) The physician shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician shall provide the patient with information on where to obtain overdose reversal drugs without a prescription.

(F) In addition to paragraphs (A) to (E) of this rule, the physician who provides OBOT using buprenorphine products shall comply with the following requirements:

(1) Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician who treats the opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products for use in OBOT.

(2) The physician may prescribe buprenorphine without naloxone (buprenorphine

mono-product) only in the following situation:

(a) When a patient is pregnant or breast-feeding;

(b) When converting a patient from buprenorphine mono-product to buprenorphine/naloxone combination product;

(c) In formulations other than tablet or film form for indications approved by the United States food and drug administration; or

(d) When the patient has a genuine allergy to or intolerance of a buprenorphine/naloxone combination product.

(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, gabapentin, or tramadol, the physician shall only co-prescribe these substances when it is medically necessary.

(a) The physician shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including whether acceptable alternative treatments are available and whether it is possible to lower the dose or discontinue the drug. If the physician prescribing buprenorphine is the prescriber of the other drug, the physician shall also consider these options and consider consultation with another healthcare provider. The physician shall educate the patient about the serious risks of the combined use.

(b) The physician shall document the rationale for discontinuing, lowering, or continuing the medication given potential risks and benefits.

(4) During the induction phase the physician shall not prescribe a dosage that exceeds the recommendation in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the patient record. The physician shall see the patient at least once a week during this phase.

(5) During the maintenance phase, the physician shall prescribe a dosage of buprenorphine that avoids intoxication or sedation, prevents withdrawal, and suppresses significant drug craving. For the first twelve months of treatment, the physician shall prescribe no more than a one-month supply of the buprenorphine product unless utilizing a formulation with duration of action exceeding one month, such as injections or implants.

~~(a) During the first ninety days of treatment, the physician shall prescribe no more than a two-week supply of the buprenorphine product, unless utilizing a formulation with duration of action exceeding two weeks, such as injections or implants.~~

~~(b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician shall prescribe no more than~~

~~a thirty-day supply of the buprenorphine product, unless utilizing a formulation with duration of action exceeding thirty days, such as injections or implants.~~

(6) The physician shall reduce the risk of buprenorphine diversion by using the lowest effective dose, and by using one or more of the following: scheduling appropriate frequency of office visits, conducting random pill counts, checking OARRS and utilizing drug testing, serum medication levels, and oral fluid testing to assess for patient adherence to prescribed buprenorphine treatment.

(7) When using any sublingual formulation of buprenorphine, the physician shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day, unless the prescriber is an addiction specialist physician, or a consultation has been obtained from such a specialist recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine per day.

(8) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

(9) The physician may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

(a) The physician shall strictly comply with any required risk evaluation and mitigation strategy program for the drug.

(b) The physician shall prescribe an extended-release buprenorphine product strictly in accordance with the United States food and drug administration's approved labeling for the drug's use.

(c) The physician shall document in the patient record the rationale for the use of the extended-release buprenorphine product

(d) The physician who orders or prescribes an extended-release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care professional acting in accordance within the scope of their professional license.

4731-33-03 **Office-based treatment for opioid addiction.**

(A) A physician who provides OBOT shall comply with all of the following requirements:

(1) Before initiating OBOT, the physician shall comply with section 3719.064 of the Revised Code.

(2) Comply with all federal and state laws and regulations governing the prescribing of the medication; and

(3) Complete at least eight hours of "Category 1" continuing medical education relating to substance abuse and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the physician's "Category 1" continuing medical education requirement for biennial renewal of the physician's license.

(B) The physician who provides OBOT shall perform and document an assessment of the patient.

(1) The assessment shall include all of the following:

(a) A comprehensive medical and psychiatric history;

(b) A brief mental status exam;

(c) Substance abuse history;

(d) Family history and psychosocial supports;

(e) Appropriate physical examination;

(f) Urine drug screen or oral fluid drug testing;

(g) Pregnancy test for women of childbearing age and ability;

(h) Review of the patient's prescription information in OARRS;

(i) Testing for human immunodeficiency virus;

(j) Testing for hepatitis B;

(k) Testing for hepatitis C; and

(l) Consideration of screening for tuberculosis and sexually-transmitted diseases in patients with known risk factors.

(2) For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and pregnancy test, the physician may satisfy the assessment requirements by reviewing records from a physical examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit.

(3) If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician shall document the reasons in the medical record.

(C) The physician who provides OBOT shall establish and document a treatment plan that includes all of the following:

(1) The physician's rationale for selection of the specific drug to be used in the medication-assisted treatment;

(2) Patient education;

(3) The patient's written, informed consent;

(4) Random urine-drug screens;

(5) A signed treatment agreement that outlines the responsibilities of the patient and the physician; and

(6) A plan for psychosocial treatment, pursuant to paragraph (E) of this rule.

(D) The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

(1) SAMHSA treatment improvement protocol publications for medication assisted treatment available from the SAMHSA website at: https://store.samhsa.gov.

(2) "National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," approved by the American society of

addiction medicine in 2015, available from the website of the American society of addiction medicine at https://www.asam.org/.

(E) Except if the physician providing OBOT is a board certified addictionologist, board certified addiction psychiatrist, or psychiatrist, the physician shall refer and work jointly with a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as those terms are defined in rule 4731-33-01 of the Administrative Code, to determine the optimal type and intensity of psychosocial treatment for the patient and document the treatment plan in the patient record.

(1) The treatment shall, at a minimum, include a psychosocial needs assessment, supportive counseling, links to existing family supports, and referral to community services.

(2) The treatment shall include at least one of the following interventions, unless reasons for exception are documented in the patient record:

(a) Cognitive behavioral treatment;

(b) Community reinforcement approach;

(c) Contingency management/motivational incentives;

(d) Motivational interviewing; or

(e) Behavioral couples counseling.

(3) The treatment plan shall include a structure for revision of the treatment plan if the patient does not adhere to the original plan.

(4) When clinically appropriate and if the patient refuses treatment from a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as defined in rule 4731-33-01 of the Administrative Code, the physician shall ensure that the OBOT treatment plan requires the patient to participate in a twelve step program or appropriate self-help recovery program. If the patient is required to participate in a twelve step program or self-help recovery program, the physician shall require the patient to provide documentation of on-going participation in the program.

(5) Additional requirements related to the provider of behavioral health services:

(a) If the physician providing OBOT is a board certified addictionologist, psychiatrist, or board certified psychiatrist, the physician may personally provide behavioral health services for addiction.

(b) If the physician refers the patient to a qualified behavioral healthcare provider, community addiction services provider, or community mental health services provider, the physician shall document the referral and the physician's maintenance of meaningful interactions with the provider in the patient record.

(F) The physician who provides OBOT shall offer the patient a prescription for a naloxone kit.

(1) The physician shall ensure that the patient receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(2) The physician shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.

(3) The physician shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician shall provide the patient with information on where to obtain a kit without a prescription.

(G) In addition to paragraphs (A) to (F) of this rule, the physician who provides OBOT using buprenorphine products shall comply with all of the following requirements:

(1) The provision shall be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician who treats the opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products for use in OBOT.

(2) The physician shall prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations, and shall fully document the

evidence for the decision to use buprenorphine mono-product in the medical record:

(a) When a patient is pregnant or breast-feeding;

(b) When converting a patient from buprenorphine mono-product to buprenorphine/naloxone combination product;

(c) In formulations other than tablet or film form for indications approved by the United States food and drug administration;

(d) For withdrawal management when a buprenorphine/naloxone combination product is contraindicated, with the contraindication documented in the patient record; or

(e) When the patient has an allergy to or intolerance of a buprenorphine/naloxone combination product, after explaining to the patient the difference between an allergic reaction and symptoms of opioid withdrawal precipitated by buprenorphine or naloxone, and with documenation included in the patient record.

(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, or tramadol, the physician shall only co-prescribe these substances when it is medically necessary.

(a) The physician shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including whether it is possible to taper the drug to discontinuation. If the physician prescribing buprenorphine is the prescriber of the other drug, the physician shall taper the other drug to discontinuation, if it is safe to do so. The physician shall educate the patient about the serious risks of the combined use.

(b) The physician shall document progress with achieving the tapering plan.

(4) During the induction phase the physician shall not prescribe a dosage that exceeds the recommendaton in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the patient record. The physician shall see the patient at least once a week during this phase.

(5) During the stabilization phase, when using any oral formulation of buprenorphine, the physician shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

(a) During the first ninety days of treatment, the physician shall prescribe no more than a two-week supply of the buprenorphine product containing naloxone.

(b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician shall prescribe no more than a thirty-day supply of the buprenorphine product containing naloxone.

(6) The physician shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of OARRS. The physician shall require urine drug screens, serum medication levels, or oral fluid testing at least twice per quarter for the first year of treatment and at least once per quarter thereafter.

(7) When using any oral formulation of buprenorphine, the physician shall document in the medical record the rationale for prescribed doses exceeding sixteen milligrams of buprenorphine per day. The physician shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day.

(8) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

(9) The physician may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

(a) The physician shall strictly comply with any required risk evaluation and mitigation strategy program for the drug.

(b) The physician shall prescribe an extended-release buprenorphine product strictly in accordance with the United States food and drug administration's approved labeling for the drug's use.

(c) The physician shall document in the patient record the rationale for the

use of the extended-release buprenorphine product.

(d) The physician who orders or prescribes an extended-release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care professional acting in accordance with the scope of the professional license.

4731-33-04 **Medication-assisted treatment using naltrexone.**

(A) In addition to the requirements of paragraphs (A) to (E) of rule 4731-33-03 of the Administrative Code, the physician using naltrexone to treat opioid use disorder shall comply with the following requirements:

(1) Before initiating naltrexone, the physician shall take measures to ensure that the patient is opioid abstinent for an adequate period of time after completing opioid withdrawal to avoid precipitated withdrawal. The physician shall alert the patient of the risk of potentially lethal opioid overdose if they stop naltrexone and use opioids.

(2) The physician shall use oral naltrexone only for treatment of patients who are highly motivated.

(a) The dosage regime shall strictly comply with the food and drug administration approved labeling for naltrexone hydrochloride tablets.

(b) The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.

(c) The physician shall ~~conduct random pill counts and~~ require urine drug screens, serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

(d) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

(B) The physician may treat a patient with extended-release naltrexone for opioid or alcohol dependence or for co-occurring opioid and alcohol use disorders.

(1) The physician should consider treatment with extended-release naltrexone for patients who have difficulties with treatment adherence.

(2) The dosage shall strictly comply with the United States food and drug administration approved labeling for extended-release naltrexone.

(3) The physician shall determine the effectiveness of treatment with extended-release naltrexone by utilizing drug testing, serum medication levels, and oral fluid testing throughout the course of treatment.

(4) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider,

as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

4731-33-04 **Medication-assisted treatment using naltrexone.**

(A) In addition to the requirements of paragraphs (A) to (F) of rule 4731-33-03 of the Administrative Code, the physician using naltrexone to treat opioid use disorder shall comply with all of the following requirements:

(1) Prior to treating a patient with naltrexone the physician shall inform the patient about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids. The physician shall take measures to ensure that the patient is adequately detoxified from opioids and is no longer physically dependent prior to treatment with naltrexone.

(2) The physician shall use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated.

(a) The dosage regime shall strictly comply with the food and drug administration approved labeling for naltrexone hydrochloride tablets.

(b) The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.

(c) The physician shall require urine drug screens,serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

(d) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualifed behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

(B) The physician may treat a patient with extended-release naltrexone for opioid dependence or for co-occuring opioid and alcohol use disorders.

(1) The physician should consider treatment with extended-release naltrexone for patients who have issues with treatment adherence.

(2) The injections dosage shall strictly comply with the United States food and drug administration approved labeling for extended-release naltrexone.

(3) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider,

as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

April 18, 2024

Kimberly Anderson, Chief Legal Officer
Ohio State Medical Board
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Sent via Email to Medical Board at: Kimberly.Anderson@med.ohio.gov

RE: Proposed Rules 4731-33: 01-04

Dear Ms. Anderson,

Thank you for the opportunity to comment on Rules 4731-33: 01-04—Office Based Treatment for Opioid Addiction. We were glad to see that the Board has proposed many of the changes that we believe will help improve addiction care in Ohio.

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO), founded in 1824, is the region's professional medical association and the oldest professional association in Ohio. We are a non-profit 501(c)6 representing over 6,700 physicians and medical students from all the contiguous counties in Northern Ohio. We are proud to be the stewards of Cleveland's medical community of the past, present, and future.

The mission of the AMCNO is to support physicians in being strong advocates for all patients and to promote the practice of the highest quality of medicine. With that in mind, we offer the following comments.

As per our previous comments, we were very glad to see the Board's decision to amend the behavioral health treatment requirements and raise the buprenorphine daily dosage ceiling. We believe both of these decisions will make treatment more accessible to patients by helping reduce care delays and giving providers clinically appropriate room to adjust prescriptions.

However, we would like to reiterate our respectful disagreement with the Board's decision to retain the requirements for 8 hours of CME related to substance use disorder and addiction every two years for physicians and physician assistants providing office-based opioid treatment. We believe that this requirement is an unnecessary burden to potential prescribers that may ultimately limit the number of prescribers that can offer this treatment. As the opioid crisis continues in Ohio, we believe it is as important as ever to ensure we have an ample treatment workforce that is ready and able to respond to the needs of the community.

We found in our analysis of state policies regarding office based opioid treatment that Ohio has one of the more burdensome sets of requirements in the country, surpassing even the new federal CME standard. The Ohio CME requirement, particularly with the need to renew every two years, represents even more barriers than the federal MATE Act requirement of a one-time 8-hour training. We strongly urge the Board to reconsider this requirement.

Thank you for this opportunity to provide comments and for your continued work towards improving addiction outcomes in Ohio.

Sincerely,

Jen Johns, MPH
AMCNO Executive Director

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RE: Opioid Treatment Rules for Physicians and Physician Assistants
4/18/2024

Dear Director Loucka and the Common Sense Initiative Office,

We, a collective of primary care physicians, psychiatrists, pharmacists, and addiction specialists, bring a wealth of expertise and experience to the table in the treatment of caring for individuals with substance use disorders. We appreciate the opportunity to comment on the State Medical Board of Ohio's proposed office-based opioid treatment rules. Our practices span across the state, where we all provide evidence-based addiction care. It's worth noting that most buprenorphine in the US is prescribed by primary care practitioners and psychiatrists, not addiction specialists.[1]

We write to the CSI and SMB as a group of outpatient physicians at diverse institutions. Our shared goal is to provide feedback that can enhance these rules, thereby increasing the number of physicians willing to prescribe buprenorphine in their practice. Feedback from our colleagues has highlighted the current regulations as a barrier to providing safe and life-saving treatment for substance use disorders.

We provide comments with the hope of increasing the uptake of addiction care throughout our state, in urban, suburban, and rural areas, to expand access to evidence-based addiction treatment.

We are grateful for the opportunity to provide our comments and your time and consideration.

Sincerely,

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Specific comments:

4731-33-0w Standards and procedures for withdrawal management for substance use disorder

Proposed Rule:
(E)(2) "The physician shall provide ambulatory withdrawal management under a defined set of policies and procedures or medical protocols consistent **w**ith American society of addiction medicine's level I-WM or II-WM level of care, under which services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a drug, and to effectively facilitate the patient's transition into treatment and recovery. The ASAM criteria, fourth edition, can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours."

Comment:
ASAM levels of care are intended to define treatment locations (e.g., residential, outpatient, etc) and are not utilized as medical treatment protocols, yet the proposed rules imply that they could serve as a medical protocol, policy, or procedure. Addiction specialists use this terminology to help determine which "location type" a patient can utilize. These levels are often not applicable in many parts of our state that lack access to specialty treatment centers. We recommend the following revision to make it more applicable to generalists who provide addiction treatment.

Proposed Revision:
(E)(2) "The physician shall provide ambulatory withdrawal management**, if deemed safe, by including an assessment of their risk of severe withdrawal. This can be done by clearly documenting the clinical rationale and judgment of the provider. Additionally, the ASAM criteria can be used to help identify the best level of care for patients (outpatient, residential, or hospital-based withdrawal management).** The ASAM criteria, fourth edition, can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours."

Proposed Rule:
(E)(11) "The physician shall take steps to reduce the risk of medication diversion by using frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS."

Comment:
We are concerned that the way this provision is currently written, clinicians must be able to complete all the items listed to minimize diversion. We suggest a revision to clarify how this provision should apply in setting where all of these actions might not be practicable. For example, outpatient offices may be unable to complete all these methods to minimize diversion, because of lack of appointments and support staff to implement. Primary care practices may have challenges performing random pill counts, because pill counts require office staff to call a patient, have them present to the clinic within 24 hours, and have staff make a separate appointment to complete the pill count with the patient, and this is time that could be spent performing other clinical duties. In addition, this is often not a billable service if a nurse or medical assistant completes this task.

Proposed Revision:

The physician shall take steps to reduce the risk of medication diversion, **which may include** frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS. **Physicians can select tools to minimize diversion depending on the clinical scenario and practice environment.**

4731-33-03 Office-based opioid treatment.

Proposed Rule:
(A)(3) “Complete at least eight hours of "Category 1" continuing medical education relating to substance use disorder and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the physician's "Category 1" continuing medical education requirement for biennial renewal of the physician's license”

Comment:
We recommend rescinding this regulation in light of the DEA’s new 8-hour requirement on SUD education, The proposed requirement of repeating training every two years is unnecessarily burdensome. Even previously, the x-waiver only mandated a one-time 8-hour educational training requirement at a federal level to prescribe buprenorphine. We believe the DEA’s current, one-time 8-hour training requirement is adequate training to manage simple, straightforward cases of opioid use disorder. Feedback from colleagues suggests that excessive training requirements have limited the prescriptions of buprenorphine in our state as well as decreased bridge prescriptions to treatment formal treatment settings while patients are waiting for appointments. It can sometimes take months or longer for patients to access formal treatment settings due to a lack of specialty treatment access. We want to ensure that generalists can provide bridge scripts and start immediate patient treatment.

Proposed Revision:
Rescind this proposed requirement. The federal standards for a one-time, 8-hour educational requirement on substance use disorders to obtain a DEA license are sufficient.

Proposed Rule:
(B)(3) “The patient's written, informed consent.”

Comment:
Currently, there are two documents required: a signed treatment agreement and signed informed consent. Signed informed consent in medicine is often limited to procedures and is not considered a standard of care for medication management. This documentation requirement is also excessively burdensome in busy outpatient offices, so we recommend requiring the signed treatment agreement only.

Proposed Revision:
Rescind this provision.

Proposed Rule:
(C) “The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering.
Acceptable protocols are any of the following:
(1) TIP 63 “Medications for Opioid Use Disorder” (2021) available from the

https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002.
(2) "ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update," available from the website of the American society of addiction medicine at https://www.asam.org/quality-care/clinical-guidelines /national-practice-guideline."

Comment:
Given the pace of new research and a changing drug supply, our concern is that this language is too specific and does not allow clinicians to integrate the latest research into their practice, which may be necessary if a patient has a treatment failure on one of the standard protocols listed in the document. We suggest adding another standard protocol from ASAM on OUD treatment from 2023,[2] adding a line to support that updated protocols from SAMHSA and ASAM can be utilized, and adding a line that if there is deviation from the protocols listed, that rationale be documented.

Proposed Revision:
(C) The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. **Should a physician utilize a different protocol for induction, stabilization, maintenance, and tapering than the ones described, they should document the rationale and patient-shared decision-making for why they are using a different approach.**

Acceptable protocols are any of the following:
(1) TIP 63 "Medications for Opioid Use Disorder" (2021) available from thehttps://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002. **Or the most updated version of this document**

(2) "ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update," available from the website of the American society of addiction medicine at https://www.asam.org/quality-care/clinical-guidelines /national-practice-guideline. **Or the most updated version of this document**

(3) "ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids, which can be found here: https://pubmed-ncbi-nlm-nih-gov.uc.idm.oclc.org/37934520/ **Or the most updated version of this document**

Proposed Rule:
(F) "In addition to paragraphs (A) to (E) of this rule, the physician who provides OBOT using buprenorphine products shall comply with the following requirements:

(5) During the maintenance phase, the physician shall prescribe a dosage of buprenorphine that avoids intoxication or sedation, prevents withdrawal, and suppresses significant drug craving.

(a) During the first ninety days of treatment, the physician shall prescribe no more than a two-week supply of the buprenorphine product, unless

utilizing a formulation with duration of action exceeding two weeks, such as injections or implants.
(b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician shall prescribe no more than a thirty-day supply of the buprenorphine product, unless utilizing a formulation with duration of action exceeding thirty days, such as injections or implants."

Comment: The motivation behind this requirement is commendable; patients with opioid use disorder should be seen and evaluated frequently. Early treatment is a high-risk period for those initiating buprenorphine-containing medications, as precipitated withdrawal can drive people away from these life-saving medicines. This rule doesn't make it clear if the purpose of limited supply during this period is to promote frequent patient evaluation or to limit the supply of buprenorphine-containing medications during an acclimation period. We must balance this with at least two opposing factors: First, the system-level issue of sub-optimal access to primary care providers. For many, getting a two-week follow-up appointment is quite difficult, especially when other interruptions in care are considered, such as physician vacations or temporarily reduced clinic time if a primary care physician also rotates on a hospital service.

We recommend the board reconsider the limitation of only prescribing a two-week supply. Patients early in treatment may typically receive a two-week supply; however, there are situations, such as patient travel, transportation issues, physician holidays, appointment availability, or transitioning into a maintenance phase of treatment, where longer prescriptions beyond 14 days before completing a full 90-day treatment may be appropriate.

Proposed Revision 1: Make the purpose behind this clear. If the two-week prescription does not require a physician evaluation it should be stated as such.

Proposed Revision 2: Allow flexibility in who can evaluate patient if the intent is for two-week evaluations during the first 90 days or monthly evaluations in the first year.

Proposed Text Revision: (a) During the first ninety days of treatment, the **physician shall provide appropriate follow-up and assessment of the patient based on multiple clinical and environmental factors to determine the appropriate duration of a buprenorphine prescription. Assessment can be either office-based or remote evaluation by a physician or staff associated with the treating physician (such as a clinic social worker or nurse).**

Proposed Rule:
F(2): The physician may prescribe buprenorphine without mono-product only in the following situations…

Comment:
We support expanding access to sublingual buprenorphine mono-product prescriptions with fewer restrictions. Updated evidence suggests that the historical concern of injection misuse and diversion are misguided when comparing the combination vs mono product. The addition of naloxone in a buprenorphine product does not necessarily deter misuse in real-life scenarios.[3] In addition, the addition

of naloxone is not entirely benign and can have negative consequences.[4] Often, the mono-product of buprenorphine is better tolerated by patients and may make it easier to start buprenorphine.

Proposed Revision: Rescind parts F 2a-d

Proposed Rule:
(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative-hypnotics, carisoprodol**,** gabapentin, or tramadol, the physician shall only co-prescribe these substances when it is medically necessary.

Comment: We recommend removing gabapentin from the list of medications that should not be co-prescribed with buprenorphine. Gabapentin is a medication frequently used to treat neuropathic pain, and many individuals with opioid use disorder have chronic pain syndromes. Uncontrolled pain can lead to individuals trying to self-medicate with an illicit drug supply. In a recent study, individuals with OUD on buprenorphine and co-prescribed gabapentin was not associated with an increased risk of drug-related poisoning.[5] At this time, the benefit of gabapentin likely outweighs the risk if there is an indication for an individual on buprenorphine to be on this medication.

Proposed Revision
(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative-hypnotics, carisoprodol**,** or tramadol, the physician shall only co-prescribe these substances when it is medically necessary.

Proposed Rule:
F(7) When using any sublingual formulation of buprenorphine, the physician shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day, unless the prescriber is an addiction specialist physician, or a consultation has been obtained from such a specialist recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine per day

Comment: In our state, which has large swaths of rural areas and a lack of addiction-trained specialists, we recommend removing this requirement; we feel that this requirement is impractical in our state with our current specialist workforce shortages. There is evidence to support using 32mg daily of buprenorphine for maintenance, and we do not feel that an addiction specialist should be required to sign off on using this dose.[6] In addition, occasionally in our clinical experiences, we have used up to 40mg on day 1 of induction for patients who have experienced precipitated opioid withdrawal in the monitored hospital setting, and in this clinical scenario, patients temporarily benefited from a higher dose. Or suppose a patient accidentally swallowed buprenorphine rather than taking the medication sublingually. In that case, we have had to give additional doses to account for this non-optimal absorption of the medication (e.g., buprenorphine has minimal absorption if someone accidentally swallows it).

Proposed Revision:
F(7) When using any sublingual formulation of buprenorphine, the physician shall not prescribe a dosage exceeding **32 milligrams of buprenorphine per day, unless the clinical rationale is documented in the note**

4731-33-04 Medication-assisted treatment using naltrexone.

Proposed Rule:
(2) (c) **"**The physician shall conduct random pill counts and require urine drugs screens, serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

Comment: Naltrexone is not a controlled substance, and it can be burdensome to require random pill counts. This requires office staff to call a patient, have them present to the clinic within 24 hours, and have staff make a separate appointment to complete the pill count with the patient, and this is time that could be spent performing other clinical duties. In addition, this is often not a billable service if a nurse or medical assistant completes this task, and it is not a good use of a physician's time. We recommend removing this clause since it is burdensome, and there is no concern for public safety if naltrexone is diverted. We recommend removing the specific frequency of urine drug screens and deferring to clinical judgment since this medication is not a controlled substance. There can be variable clinical scenarios that could prevent a patient from obtaining a urine drug screen on a specified schedule, and the risks of cessation of naltrexone, such as overdose and death, make the risks of cessation very high in comparison to the benefit of continuing the medication.

Proposed revision: "The physician **can utilize urine drug screens,** serum medication levels, or oral fluid **drug testing to help monitor treatment effectiveness.**

References:

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2. Weimer MB, Herring AA, Kawasaki SS, Meyer M, Kleykamp BA, Ramsey KS. ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids. *Journal of Addiction Medicine*. 2023:10.1097.
3. Blazes CK, Morrow JD. Reconsidering the Usefulness of Adding Naloxone to Buprenorphine. *Front Psychiatry*. 2020;11:549272. doi:10.3389/fpsyt.2020.549272
4. Gregg J, Hartley J, Lawrence D, Risser A, Blazes C. The naloxone component of buprenorphine/naloxone: discouraging misuse, but at what cost? *Journal of addiction medicine*. 2023;17(1):7-9.
5. Ellis MS, Xu KY, Tardelli VS, Fidalgo TM, Buttram ME, Grucza RA. Gabapentin Use Among Individuals Initiating Buprenorphine Treatment for Opioid Use Disorder. *JAMA psychiatry*. 2023;80(12):1269-1276.
6. Grande LA, Cundiff D, Greenwald MK, Murray M, Wright TE, Martin SA. Evidence on Buprenorphine Dose Limits: A Review. *J Addict Med*. Jun 16 2023;doi:10.1097/adm.0000000000001189

From:	Dennis Helmuth
To:	Anderson, Kimberly; CSIPublicComments
Subject:	Comments
Date:	Saturday, April 6, 2024 3:27:37 PM
Attachments:	Business_Impact_Analysis_and_Attachments.pdf

See attached. Twice the regulations refer to "addiction psychologists" as prescribers. Psychologists do not prescribe. This should be addiction psychiatrists.

Dr. Helmuth

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Dennis Helmuth, MD, PhD
Wooster, Ohio

Ohio Society of Addiction Medicine
A Chapter of American Society of Addiction Medicine

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April 18, 2024

RE: Opioid Treatment Rules for Physicians and Physician Assistants

The Ohio Chapter of the American Society of Addiction Medicine (OHSAM) is a chapter of the American Society of Addiction Medicine (ASAM). ASAM is a professional society that has over 7,500 members consisting of specialists and providers who focus on treating patients with substance use disorders. The advocacy committee of OHSAM applauds key updates in the Ohio Outpatient Addiction Regulations, removing the required psychosocial support in the current office-based buprenorphine treatment regulation. In addition, we agree with changing the buprenorphine dosage cap from 16mg to 24mg and up to 32mg if done in conjunction with an addiction specialist. We believe the newly proposed revisions help decrease the current documentation burden in providing office-based addiction treatment.

We have additional comments that we ask the CSI and State Medical Board to consider in the context of addiction treatment in our state. We believe that there is "no wrong door" to engaging in substance use disorder (SUD) treatment. Our state is comprised of urban, suburban, and rural areas, and large swaths of our state lack public transportation. Many parts of rural Ohio have no access to addiction specialists. Most buprenorphine for the treatment of opioid use disorder (OUD) in the U.S. is not prescribed by addiction specialists but rather by outpatient primary care providers and general psychiatrists.[1] With opioid overdose deaths continuing to rise, as well as an increase in alcohol use in our state, our comments focus on ways to improve these regulations to increase the uptake of general practitioners who will provide medical treatment safely for individuals with substance use disorders.

We have heard from our generalist colleagues that these regulations discourage clinicians from providing office addiction treatment, as they feel they are burdensome, particularly for clinical practices in rural areas, small practices, and settings where they may only care for a handful of patients with addiction. They have commented that the current regulations make it "not worth the hassle," and in rural Ohio, this could mean patients have no access to any addiction treatment. Furthermore, we hope to train physicians in training during their residency on SUD management and encourage clinicians in different settings, such as the emergency room, urgent care, and other outpatient settings, to provide bridge treatment services while patients are pending an appointment in a specialized addiction treatment setting.

We believe the following comments would decrease the regulatory burden and expand access and uptake of general practitioners who will provide office-based addiction treatment safely. Notably, only ten states have office-based addiction treatment regulations, supporting the idea that decreasing the regulatory burden can be done safely.

We have the following key concerns with the proposed rules.

- 8-hour CME requirement every two years for office-based opioid treatment
- Use of language and lack of flexibility for diverse treatment settings that can be misinterpreted, and discourages outpatient physicians such as internists and family med from providing evidence-based addiction care

- Lack of flexibility to adapt to the evolving drug supply as these regulations are reviewed on a 5-year cycle.
- Changing terminology of ASAM's Levels of Care in 2024

CME

Currently, there is an 8-hour CME requirement every two years for physicians to office-based opioid treatment (OBOT). We understand the importance of ensuring that healthcare providers maintain competency in prescribing medications for opioid use disorder (OUD) yet uphold that this stringent CME requirement poses unnecessary barriers to access for patients in need of treatment. The substantial time and financial investments necessary to fulfill this state mandate discourage clinicians from prescribing buprenorphine, particularly for practitioners in the following scenarios: 1) outpatient practitioners whom would care for a small number of patients (e.g. five patients, which could particularly cause an addiction treatment access issue in rural Ohio) 2) practitioners who would care for individuals temporarily (e.g. 1-4 weeks) as a bridge to their appointment in a specialized treatment setting 3) busy outpatient primary care and general psychiatry practices who have a wide breadth of requirements to fulfill.

In the recent setting, the CARA Act of 2023 requires that all DEA-licensed practitioners who prescribe controlled substances, such as buprenorphine, undergo 8 hours of CME education on substance use disorders. OBOT medications have been around for over 20 years, and there are 3-key medications for a clinician to be familiar with and the pharmacology principles of how they work will remain unchanged, supporting that every 2-year CME requirement is redundant. In comparison, within our own state, only 2 hours of CME once is required to become certified to endorse medical marijuana for patients.

We ask the CSI and SMB to consider rescinding this requirement entirely in the setting of the new, existing DEA requirement on 8 hours of CME for addiction education, or at a minimum, rescind it for the following scenarios: prescriptions as an intent to bridge the patient to a formal treatment which may include the emergency room, hospital discharges, urgent care, residents under the supervision of an attending, and other outpatient practices.

Language & Flexibility to Adapt Protocols:

Addiction treatment can be provided in a variety of settings ranging from formal treatment settings to outpatient primary care or psychiatry practices. Different settings have different resources, use different language, and have varying structures, and we support that there is "no wrong door" to addiction treatment. At times, when reading the regulations, it is unclear and confusing to outpatient practitioners who tend to have less support or a formal structured process to meet some of the requirements (e.g., primary care docs who care for a small number of patients on buprenorphine). We have provided several comments below designed to lessen the barrier to providing outpatient addiction treatment.

Evolving Drug Supply:

Over the past few years, due to the changing drug supply in the U.S., new research has supported new ways to initiate buprenorphine safely, in addition to the existing standards. Fentanyl has unique properties that can make buprenorphine initiations more challenging, and these regulations references, such as "SAMHSA TIPS 63" and "ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update," are already considered out of date. ASAM introduced new clinical considerations in 2023 to fill this gap, describing two additional methods to start buprenorphine: high-dose and low-dose/overlapping initiations.[2] Within three years, the ASAM guidelines referenced in this regulation have already had a new supplement via these clinical considerations. In our state, we are already starting to see an increase in xylazine in our illicit drug supply, which may further change how we treat withdrawal and substance use disorders.

These regulations are only reviewed every five years. Our concern is that the way section C (1)(2)of the Office Based Opioid Treatment section is already out of date in this portion "(C) The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following: (1) TIP 63 "Medications for Opioid Use Disorder" (2021) (2) "ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update.

Please see our specific comments below for 4731-33-03 Office-based opioid treatment on this topic.

We anticipate that there may be new methods to start buprenorphine or treat new illicit substances such as xylazine before the next 5-year review. We feel strongly that clinicians who are keeping up with new research, and in particular for patients who may have already had unsuccessful treatment attempts using standard protocols, that clinicians should have the ability to offer newer treatment protocols that exist in the literature. In addition, language should be included that suggests using the most recent versions of the guidelines, as the documents listed may change before the next 5-year review cycle of these regulations.

Changing Terminology regarding ASAM's Levels of Care

ASAM released a fourth edition to the ASAM Criteria Dimensions to determine the level of care in 2023 with updated terminology and significant changes. The updated levels of care are considered effective May 1st, 2024. Additional information can be found at think link: https://www.asam.org/asam-criteria. Overall, the ASAM levels of care are intended to be used to standardize treatment location definitions. They are not actually used for standards for patient assessment, nor are they considered a treatment protocol. They are often used for billing purposes, and we suggest removing the ASAM's level of care terminology entirely, as they are not intended to be used as a standard for a treatment protocol but rather are used as location of treatment definitions.

In addition, ASAM levels of care are often utilized by addiction specialists, and this terminology is not commonly used by outpatient practitioners such as outpatient primary care clinicians and general psychiatrists. The use of this term can be confusing to general practitioners. We have suggested areas to remove reference to ASAM levels of care.

Thank you,

Ted Parran MD

Dr. Ted Parran
Ohio ASAM President

Specific comments:

4731-33-02 Standards and procedures for withdrawal management for substance use disorder

(E) (2) "The physician shall provide ambulatory withdrawal management under a defined set of policies and procedures or medical protocols consistent **with American society of addiction medicine's level I-WM or II-WM level of care,** under which services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a drug, and to effectively facilitate the patient's transition into treatment and recovery. The ASAM criteria, fourth edition, can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours.

Comment: The highlighted area is outdated terminology with ASAM's newest levels of care. It does reference the correct document. However, ASAM levels of care refer primarily to the staffing, support and therapies available but not specific treatment protocols. In addition, many generalists who provide SUD care would not utilize this terminology and it could defer clinicans from offering SUD care.

Proposed Revision:
(E) (2) "The physician shall provide ambulatory withdrawal management**, if deemed safe, by including an assessment of their risk of severe withdrawal. This can be done by clearly documenting the clinical rationale and judgment of the provider. Additionally, The ASAM criteria can be used to help identify the best level of care for patients (outpatient, residential, or hospital-based**

withdrawal management). The ASAM criteria, fourth edition, can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours.

(8) "The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for use of licit and/or illicit drugs. The physician shall consider revising the treatment plan or referring a patient who has a positive toxicological screening result to a **higher level of care."**

Comment: Many generalists do not utilize terms such as higher levels of care. Please see updated language below

Proposed Revision; (8) The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for use of licit and/or illicit drugs. The physician shall consider revising the treatment plan or referring a patient who has a positive toxicological screening result to a **higher level of care such as a hospital, inpatient medically supervised withdrawal facilitates, or outpatient addiction specialty care.**

(11) "The physician shall take steps to reduce the risk of medication diversion by using frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS."

Comment: We believe that the clinician should have the option to select any of the tools listed to minimize diversion depending on the context of their practice; they should not necessarily have to be able to perform every single one of these steps. Our members are concerned that this line is interpreted that clinicians must be able to complete all the items listed to minimize diversion. We provide a revision to clarify this.

Outpatient offices may be unable to complete all of these methods to minimize diversion. For example, primary care practices may have challenges performing random pill counts. This requires office staff to call a patient, have them present to the clinic within 24 hours, and have staff make a separate appointment to complete the pill count with the patient, and this is time that could be spent performing other clinical duties. In addition, this is often not a billable service if a nurse or medical assistant is completing this task, and it is not a good use of a physician's time.

Proposed revision: The physician shall take steps to reduce the risk of medication diversion, **which may include any of the following steps,** frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS. **Physicians can select any of the following tools to minimize diversion depending on the clinical scenario and practice environment.**

(5) (c) (page 11)The physician shall take steps to reduce the risk of diversion by using frequent office visits, pill counts, urine drug screening and frequent checks of OARRS.

Comment: Please see the comment and proposed language above from 11.

(G) (1): '(1) The physician shall provide ambulatory withdrawal from alcohol with medication management only when patient has sufficient social, medical, and psychiatric stability **and when they do not have a polysubstance dependence.** The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical conditions or severe psychiatric disorders, and no history of withdrawal seizures or withdrawal delirium.

Comment: Physical dependence to a substance would not necessarily preclude ambulatory withdrawal management. For example, if a patient is stable and has OUD in remission on buprenorphine, they would have

physical dependence but could still qualify for ambulatory alcohol withdrawal. See proposed revision to appropriate medical terminology

Proposed Revision:
(G) (1): '(1) The physician shall provide ambulatory withdrawal from alcohol with medication management only when patient has sufficient social, medical, and psychiatric stability . **~~when they do not have a polysubstance dependence.~~** The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical conditions or severe psychiatric disorders, and no history of withdrawal seizures or withdrawal delirium.

(4)(c) page 6, page 14 of PDF "(c) The physician shall take steps to reduce the risk of diversion by using frequent office visits, pill counts, urine drug screening and frequent checks of OARRS.

Comment: Please see the comment from proposed language on 11

4731-33-03 Office-based opioid treatment.

(A)(3)" Complete at least eight hours of "Category 1" continuing medical education relating to substance use disorder and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the physician's "Category 1" continuing medical education requirement for biennial renewal of the physician's license

Comment: Recommend rescinding; see comments from the top of the letter. Alternatively, we suggest significantly decreasing this requirement in both time and frequency, as it is duplicative in the setting of the recent requirements of the 8-hour required SUD education from the DEA. Feedback from colleagues suggests that this has limited the prescriptions of buprenorphine in our state as well as decreased bridge prescriptions to treatment formal treatment settings while patients are waiting for appointments.

Proposed Revision: **RESCIND is our recommendation, alternatively decrease both CME hours and frequency of requirement"** Complete at **least two hours** of "Category 1" continuing medical education relating to substance use disorder and addiction every **five years**. Courses completed in compliance with this requirement shall be accepted toward meeting the physician's "Category 1" continuing medical education requirement for biennial renewal of the physician's license

(B) (3): "The patient's written, informed consent"

Comment: These regulations have 2-document requirements for a signed treatment agreement and signed informed consent. We feel this documentation is burdensome in busy outpatient offices. We recommend maintaining the signed treatment agreement only. Signed informed consent in medicine is often limited to procedures and is not considered a standard of care for medication management. For example, patients do not need to sign informed consent to start insulin for diabetes.

Proposed Revision: Rescind this line.

"(C) The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering.
Acceptable protocols are any of the following:
(1) TIP 63 "Medications for Opioid Use Disorder" (2021) available from the

https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002.

(2) "ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update," available from the website of the American society of addiction medicine at https://www.asam.org/quality-care/clinical-guidelines /national-practice-guideline."

Comment 1: As described in the general letter, due to new research and a changing drug supply, our concern is that this language is too specific, and does not give clinicians the opportunity to integrate the latest research into their practice, which may be necessary if a patient has a treatment failure on one of the standard protocols listed in the document. We suggest adding another standard protocol from ASAM on OUD treatment from 2023, adding a line to support that updated protocols from SAMHSA and ASAM can be utilized, and adding a line that if there is deviation from the protocols listed, that rationale be documented.

Proposed Revision 1:
(C) The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. **Should a physician utilize a different protocol for induction, stabilization, maintenance, and tapering than the ones described, they should document the rationale and patient-shared decision-making for why they are using a different approach.**

Acceptable protocols are any of the following:
(1) TIP 63 "Medications for Opioid Use Disorder" (2021) available from thehttps://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002. **Or the most updated version of this document**

(2) "ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update," available from the website of the American society of addiction medicine at https://www.asam.org/quality-care/clinical-guidelines
/national-practice-guideline. **Or the most updated version of this document**

(3) "ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids, which can be found here: https://pubmed-ncbi-nlm-nih-gov.uc.idm.oclc.org/37934520/ **Or the most updated version of this document**

(5) (a): "a) During the first ninety days of treatment, the physician shall prescribe no more than a two-week supply of the buprenorphine product, unless utilizing a formulation with duration of action exceeding two weeks, such as injections or implants

Comment: While this may be reasonable in a structured outpatient addiction treatment setting, this requirement is very challenging for a busy primary care clinician to perform and defers outpatient clinicians from providing this life-saving treatment. For example, primary care clinicians' appointment availability differs from formal addiction treatment settings. We feel this language should be more flexible, for example if a primary care physician has their next appointment at 16-days instead of 14, the PCP should still be able to provide 16-days of the medication to align with their next appointment.

Proposed Revision: "During the first ninety days of treatment, the physician shall **provide a limited prescription based on the stability of the patient and follow-up appointment availability. This should not exceed a three-week** supply of the buprenorphine product, unless utilizing a formulation with duration of action exceeding two weeks, such as injections or implants"

(6) The physician shall reduce the risk of buprenorphine diversion by using the lowest effective dose, scheduling appropriate frequency of office visits, conducting random pill counts, checking OARRS and utilizing drug testing, serum medication levels, and oral fluid testing to assess for patient adherence to prescribed

buprenorphine treatment.

Comment: We believe that the clinician should have the option to select any of the tools listed to minimize diversion depending on the context of their practice; they should not necessarily have to be able to perform every single one of these steps. Our members are concerned that this line is interpreted that clinicians must be able to complete all the items listed to minimize diversion. Outpatient offices may be unable to complete all of these, for example primary care practices may have challenges completing the random pill count. See prior descriptions of this concern.

Proposed revision: The physician shall take steps to reduce the risk of medication diversion, **which may include any of the following steps,** lowest effective dose, frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS. **Physicians can select any of the following tools to minimize diversion depending on the clinical scenario and practice environment.**

4731-33-04 Medication-assisted treatment using naltrexone.

(2) (c) "The physician **shall conduct random pill counts and** require urine drugs screens, serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

Comment: Naltrexone is not a controlled substance, and it can be burdensome to require random pill counts. This requires office staff to call a patient, have them present to the clinic within 24 hours, and have staff make a separate appointment to complete the pill count with the patient, and this is time that could be spent performing other clinical duties. In addition, this is often not a billable service if a nurse or medical assistant is completing this task, and it is not a good use of a physician's time. We recommend removing this clause since it is burdensome, and there is no concern for public safety if naltrexone is diverted.

Proposed revision: "The physician **shall require urine drug screens,** serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

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From: Janet Shaw
To: Loucka, Stephanie
Cc: Anderson, Kimberly; CSIPublicComments
Subject: OPPA Comments on MAT Draft Rules
Date: Friday, April 26, 2024 4:16:15 PM
Attachments: OPPA MAT Draft Rules - Comments.pdf
Importance: High

April 26, 2024

Stephanie Louka, Director
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Director Loucka,

On behalf of the Ohio Psychiatric Physician Association, whose more than one thousand physicians specializing in psychiatry, we appreciate the opportunity to provide further comments on the Board's proposed office-based opioid treatment rules. The OPPA appreciated the opportunity for three members of its Addiction Psychiatric Committee to work with the Board in May of 2023 to provide input as the draft rules were being considered. The OPPA would like to express gratitude for the Board's commitment to enhancing access to office-based treatment for opioid use disorder (OUD) with buprenorphine. Recognizing the critical importance of this initiative, we stand in support of the Board's ongoing efforts to modernize office-based OUD treatment protocols.

Buprenorphine is a safe and effective remedy, crucial in mitigating the adverse effects of OUD and significantly reducing the risk of accidental overdose. There is an alarming rise in opioid-related fatalities among some of Ohio's most vulnerable demographics, including pregnant women and new mothers. It is evident that swift action is imperative to address this pressing issue, and the proposed regulations signify a step in the right direction.

While encouraged by the proposed changes to the rules, we offer the following comments that we hope the Board will take into consideration:

- We commend the Board for the increase in the maximum daily oral dose of buprenorphine to 32 mg per day However, we propose removal of the requirement for an addiction specialist consultation to exceed the 24 mg threshold, as such a consultation is unnecessary for physicians already working within the field of addiction medicine. We appreciate the clarification allowing for the initiation of office-based opioid treatment prior to the completion of a full assessment and lab testing. This adjustment serves to diminish barriers to care and addresses the critical need for continuity of treatment, particularly during transitions from hospital or inpatient substance use disorder facilities. Furthermore, we support the amendments to the behavioral health treatment section, emphasizing the importance of

patient-centered care and flexibility in treatment modalities.

We respectfully urge the reconsideration of limitations imposed on the prescription of sublingual buprenorphine mono-products. Clinical decisions regarding medication selection should be informed by individual patient needs rather than regulatory constraints. Evidence suggests that concerns regarding misuse and diversion of mono-formulated buprenorphine may be overstated, and its accessibility could significantly aid in combating the overdose crisis.

- We also respectfully encourage the Board to reconsider the restriction of the co-prescription of gabapentin with buprenorphine. Chronic pain afflicts a significant proportion of individuals with OUD, and effective pain management is crucial in preventing relapse and reducing the risk of adverse outcomes. The benefits of adjunctive non-opioid analgesics like gabapentin outweigh the potential risks, particularly in patients with co-morbid OUD and chronic pain.

- Lastly, we urge the Board to reconsider the limitation on the initial supply of buprenorphine to a two-week period during the first 90 days of treatment. Flexibility in prescribing practices is essential to accommodate individual patient needs and ensure continuity of care throughout the critical initial stages of treatment.

In conclusion, while the OPPA encourages the Board to consider the above comments, we extend our support for the proposed rules aimed at enhancing access to office-based treatment for OUD. We remain committed to collaborating with the Board to implement policies that prioritize patient well-being and facilitate comprehensive, evidence-based care in the treatment of substance use disorder and other mental illnesses.

Thank you for your attention to these important matters.

Sincerely,

Alyse Stolting, MD
President

Janet Shaw, MBA
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From:	Gilligan, Stephanie
To:	Anderson, Kimberly; CSIPublicComments
Subject:	OSUWMC comments on Medical Board opioid treatment rules
Date:	Friday, April 19, 2024 3:17:22 PM
Attachments:	image001.png OSUWMC SMBO OBOT rules April 19 2024 FINAL.pdf

Good afternoon,

Attached please find comments from The Ohio State University Wexner Medical Center on the Medical Board's proposed opioid treatment rules.

We appreciate the opportunity share this feedback with you and are available to answer any additional questions you may have.

Thanks,
Stephanie

Stephanie Gilligan
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THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

April 19, 2024

Stephanie Loucka, Director
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Submitted electronically via Kimberly.Anderson@med.ohio.gov and CSIPublicComments@governor.ohio.gov

RE: Opioid Treatment Rules for Physicians and Physician Assistants

Dear Director Loucka,

On behalf of The Ohio State University Wexner Medical Center, we appreciate the opportunity to provide further comments on the State Medical Board of Ohio's proposed office-based opioid treatment rules. We appreciate the Board's work on this important issue— only 11% of the 2.5 million Americans with opioid use disorder received any medication treatment in 2020.[1]

One of the nation's leading academic health centers, The Ohio State University Wexner Medical Center offers health care services in virtually every specialty and subspecialty in medicine. Thousands of patients come to us each month for treatments and services they can't find anywhere else. Providing access to health care information is central to our research, education and patient care mission. At the Ohio State Wexner Medical Center, we're dedicated to improving health in Ohio and across the world through innovations and transformation in research, education, and patient care and community engagement.

Office-based treatment for opioid addiction proposed rules

We appreciate the Board's recognition of the importance of increasing access to office-based treatment for opioid use disorder (OUD) with buprenorphine. Buprenorphine is safe, effective, and is one of only two treatments for OUD known to reduce patients' risk of dying from accidental overdose.[2] Ohio State University researchers have found opioid overdose is a growing cause of death among some of our state's most vulnerable populations including pregnant women, new mothers, and adolescents.[3–7] Therefore, we enthusiastically support the Board in their current efforts to modernize office-based OUD treatment.

Our specific comments and recommendations include:

- We appreciate that the Board has increased the maximum daily oral dose of buprenorphine from 24 to 32 mg per day.
    - However, we disagree with requiring an addiction specialist consultation to exceed 24 mg. We know the Board is aware of the workforce challenges in the health care sector in general, and particularly in specialties related to behavioral health and addiction. The Ohio State University Wexner Medical Center serves both urban and rural areas of Ohio, including many where behavioral health resources are scarce. Requiring the prescriber to be a board-certified addiction specialist or addiction psychiatrist is so limiting as to

make the exception almost meaningless in a real-world setting. The Board does not put a limit on what dose of a full agonist opioid that a provider can prescribe for pain; limiting a provider's ability to choose a dose of buprenorphine for severe opioid use disorder that would benefit his or her patient risks undertreating the opioid use disorder. We reiterate our previous recommendation that the Board remove the additional requirements.

- We appreciate the clarification that office-based opioid treatment may be initiated prior to completion of the full assessment and lab testing to reduce barriers to access to care. Gaps in medication increase risk of relapse. For patients leaving a hospital or an inpatient SUD facility, they will need access to medications in the office-based setting right after discharge.

- We disagree with the limitations placed on the prescription of sublingual buprenorphine mono-product. We believe the decision to prescribe a mono-product or a buprenorphine/naloxone combination product is a clinical one based on a variety of factors specific to the patient. Current scientific evidence suggests that many of the historical concerns about injection misuse and diversion of mono-formulated buprenorphine were misguided. For example, large real-world studies have shown rates of misuse of these medications do not meaningfully differ and that the ratio of buprenorphine to naloxone in buprenorphine/naloxone is unlikely to deter such misuse. Instead of protecting the public, restricting access to mono-formulated buprenorphine has hindered providers in fighting the overdose crisis. Further, in the age of fentanyl driving our overdose death crisis, mono-product buprenorphine is often much better tolerated by patients clinically, allowing them to transition from illicit fentanyl to medication treatment for addiction. Researchers at Ohio State University have found that fear of withdrawal is a large driver of patient hesitance to seek addiction treatment, and use of mono-product buprenorphine can help facilitate the entry into life-saving treatment.[8] We recommend the Board reconsider these limitations.

- We support the amendments to the behavioral health treatment section to clarify that if psychosocial interventions are not available or if the patient declines to participate, the prescriber shall continue to treat the patient with buprenorphine so long as the patient adheres to other treatment requirements.

- We disagree with the decision to add gabapentin to the list of medications that should not be co-prescribed with buprenorphine. As many as 62% of patients with OUD also suffer from chronic pain.[9,10] Many more experience acute neuropathic pain caused by infections affecting their musculoskeletal system such as vertebral osteomyelitis. Uncontrolled pain is a major cause of relapse and has been linked to increased risk of overdose and death by suicide among patients with OUD.[11–13] For example, patients with uncontrolled chronic pain and OUD are 3 to 5 times more likely to relapse and die by suicide at a rate that is 3-fold higher than those with OUD alone.[14] While gabapentinoids do have misuse potential, best evidence suggests they do not increase the risk of fatal outcomes among OUD patients.[15] Therefore, the risk-benefit ratio strongly favors the use of adjunctive non-opioid analgesics like gabapentin among patients with co-morbid OUD and chronic pain.

- We recommend the Board reconsider the limitation of only prescribing a two-week supply of buprenorphine during the first 90 days of treatment. While it is often reasonable for patients early in their treatment to receive no more than a two-week supply, there are instances where it

is reasonable to give a longer prescription, such as patient travel, physician holiday, or transitioning into a maintenance phase before completion of a full 90 days.

- We recommend the Board reconsider specifying the frequency of urine drug screens required for oral naltrexone prescriptions. While this recommendation is consistent with sound clinical practice, it prohibits the use of clinical judgment when an exception may be appropriate. For example, for individuals with transportation difficulties it may be difficult to justify this requirement for a non-controlled substance. We ask that this language be amended to allow for clinician judgement in scenarios where patient variables make obtaining urine drug screens impractical or impossible, due to the risks associated with cessation of naltrexone, including risk of overdose and death.

Thank you for your consideration of our comments.

Sincerely,

Julie Teater, MD, DFAPA, FASAM
Associate Professor, Clinical
Chief Psychiatrist
Medical Director of Addiction Medicine
Addiction Medicine Fellowship Program Director
Department of Psychiatry and Behavioral Health
The Ohio State University Wexner Medical Center

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From:	Dipasquale, Anita
To:	Anderson, Kimberly
Cc:	Emrich, Lisa; Eschbacher, Lisa; Loucka, Stephanie
Subject:	RE: Medical Board Rules-Opioid Treatment
Date:	Friday, May 17, 2024 10:45:02 AM
Attachments:	image001.png image002.png image003.png image004.png image005.png image006.png

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Good morning Kim,

Thank you for the thorough analysis and organization of the comments received and for your overview during the Teams meeting (a few calls ago). I do not have any comments on this new packet of information. I see some of the comments we provided previously are reflected in this current version of the proposed rules (e.g. drop naloxone "kit").

Thank you,
Anita

Thank you,
Anita A. DiPasquale, JD
Advisory Attorney
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From: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Sent: Friday, May 3, 2024 11:39 AM
To: Shadwick, Aimee <Aimee.Shadwick@governor.ohio.gov>; Day, Douglas <douglas.day@mha.ohio.gov>; Hochstetler, Lois <Lois.Hochstetler@mha.ohio.gov>; Knipper, Jordan <Jordan.Knipper@mha.ohio.gov>; Mcnamee, Cameron <Cameron.McNamee@pharmacy.ohio.gov>; Bacon, Melissa <Melissa.Bacon@mha.ohio.gov>; Wilson, Erica <erica.wilson@odh.ohio.gov>; Moore, Sarah <Sarah.Moore@governor.ohio.gov>; Trevino, Justin <justin.trevino@mha.ohio.gov>; Lloyd, Jennifer <Jennifer.Lloyd@governor.ohio.gov>; Haller, Mary <MARY.HALLER@medicaid.ohio.gov>; Dipasquale, Anita <ADiPasquale@nursing.ohio.gov>; Eschbacher, Lisa <leschbacher@nursing.ohio.gov>; Emrich, Lisa <lemrich@nursing.ohio.gov>; Partika, Scott <Scott.Partika@governor.ohio.gov>; Schierholt, Steven <Steven.Schierholt@pharmacy.ohio.gov>; Kroninger, Debi <Debi.Kroninger@odh.ohio.gov>; Lyon, Lynne <Lynne.Lyon@medicaid.ohio.gov>; Deems, Shawna <Shawna.Deems@medicaid.ohio.gov>; Defiore-Hyrmer, Jolene <Jolene.Defiore-Hyrmer@pharmacy.ohio.gov>; Mabe, Aaron <Aaron.Mabe@governor.ohio.gov>
Cc: Loucka, Stephanie <Stephanie.Loucka@med.ohio.gov>
Subject: Medical Board Rules-Opioid Treatment

Good morning,

As discussed, attached please find two spreadsheets outlining the comments received on the Medical Board rules, copies of the comments received, and the BIA and proposed rules. We want to put this on the agenda for the Medical Board at their meeting on June 12, 2024. I would like to receive your comments by close of business on May 17, 2024. Please note that the comments are applicable to the rules in Chapter 4731-33 for physicians and Chapter 4730-4 for physician assistants. For ease of reference, the spreadsheets refer only to the rules in Chapter 4731-33, OAC.

Thank you for your input.

Kim

Kimberly C. Anderson
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State Medical Board of Ohio

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Comments on Rules in Chapter 4731-33 and 4730-4 By Rule Provision

Rule Provision	Organization	Comments	BOP Response
4731-33-02(E)(2)	UC Health; Ohio Society of Adiction Medicine	Clarify that ASAM criteria is for determining location of treatment rather than a practice protocol.	N/A
4731-33-02(E)(8)	Ohio Society of Addiction Medicine	Recommend providing more detail that a higher level of care could include a hospital, inpatient medically supervised withdrawal facilities, or outpatient addiction specialty care.	N/A
4731-33-02(E)(11)	UC Health; Ohio Society of Adiction Medicine	Recommend revision of language to clarify that all methods of steps to reduce the risk of medication diversion do not have to be completed.	Agree. Regular visits may be difficult for unhoused populations. Provide options but don't require all the steps.
4731-33-02(F)(5)(c)	Ohio Society of Addiction Medicine	Recommend revision of language to clarify that all methods of steps to reduce the risk of medication diversion do not have to be completed.	Agree. See comment above.
4731-33-02(G)(1)	Ohio Society of Addiction Medicine	Remove the phrase related to polysubstance dependence.	Agree with commeters.
4731-33-02(G)(4)(c)	Ohio Society of Addiction Medicine	Recommend revision of language to clarify that all methods of steps to reduce the risk of medication diversion do not have to be completed.	Agree.
4731-33-03(A)(3)	Academy of Medicine of Cleveland and Northern Ohio; UC Health; Ohio Society of Addiction Medicine	Rescind the requirement for 8 hours of CME related to substance use disorder and addiction every two years.	Agree. Are prescribers of opioids required to obtain regular training? If not, I'm not sure why we would apply additional requirements that could restrict access.
4731-33-03(A)(4)	OSU Wexner Medical Center; Ohio Psychiatric Physician Association	Supports clarification that OBOT may be initiated prior to completion of full assessment and lab testing.	Agree. This is important for bridge clinics.
4731-33-03(B)(3)	UC Health, Ohio Society of Adiction Medicine	Rescind the requirement for patient's written, informed consent because it is not standard of care for medication management and a signed treatment agreement is required.	N/A
4731-33-03(C)	UC Health, Ohio Society of Adiction Medicine	Recommend revision of requirement to utilize a practice protocol so that clinicians can integrate the latest research into their practice. Also add ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids as an additional acceptable protocol.	Agree.

4731-33-03(D)	Academy of Medicine of Cleveland and Northern Ohio; OSU Wexner Medical Center; Ohio Psychiatric Physician Association; Ohio Society of Addiction Medicine	Supports changes to behavioral health treatment.	N/A
4731-33-03(F)(2)	UC Health; Ohio Psychiatric Physician Association; OSU Wexner Medical Center	Rescind paragraphs (F)(2)(a)through (d) to allow for more prescribing of buprenorphine monoproduct.	Agree. We can always track this in OARRS to see if there are serious diversion issues. Treatment needs to be as accessible and available as illicit drugs if we're going to move the needle. If the drug is better tolerated for patients, clinicians should have the option. Are there similar restrictions in the opioid prescribing space where we require the use of a particular formulation?
4731-33-03(F)(3)	UC Health; Ohio Psychiatric Physician Association	Remove gabapentin from list of medications that should not be co-prescribed with buprenorphine.	Agree. Gabapentin is a drug of concern as it relates to OARRS. However, we do not consider it a drug of abuse. Rather, the collection of this drug in OARRS is intended to allow providers to track gabapentin use as it is commonly prescribed and patients often accumulate large supplies. Removing a non-opioid pain reliever from individuals who are experiencing pain may not be in the best interest of the patient.
4731-33-03(F)(5)(a)	UC Health; Ohio Society of Adiction Medicine; Ohio Psychiatric Physician Association; OSU Wexner Medical Center	UC Health: Eliminate the requirement for prescriptions to be limited to 14 days for the first 90 days and clarify that the assessment could be via telehealth or delegated to other healthcare professionals other than the prescriber. OSAM: During the first 90 days, the prescription should not exceed 3-week supply. OPPA and OSU Wexner Medical Center: Reconsider limitation of buprenorphine to a 14 day prescription in the first 90 days.	Agree. There should be some flexibility. Especially given access issues and persons who may be unhoused or have other issues accessing regular care or transportation services. Perhaps set a higher limit if they can document a reason why?
4731-33-03(F)(6)	Ohio Society of Addiction Medicine	Revise language to allow clinician to select any of the tools to reduce risk of diversion.	
4731-33-03(F)(7)	Ohio Academy of Medicine of Cleveland and Northern Ohio; Ohio Society of Addiction Medicine	Supports changes to raise buprenorphine dosage ceiling.	
4731-33-03(F)(7)	OSU Wexner Medical Center; UC Health; Ohio Psychiatric Physician Association	Supports increasing the maximum daily oral dose to 32 mg but recommend removal of requirement for consultation with addiction specialist for doses exceeding 24 mg per day.	Agree. This imposes an access issue. The alternative is the patient goes without and turns back to illicit and more potent drugs. This infomration can be tracked in OARRS to see if prescribers are simply giving out the max and not adhering to the standard of care.

4731-33-04(A)(2)(c)	UC Health; Ohio Society of Adiction Medicine, OSU Wexner Medical Center	UC Health: Remove requirement for pill counts and remove requirement for specific frequency of urine drug screens. OSAM: Remove requirement for pill counts.OSU Wexner Medical Center: Reconsider specifying the frequency of urine drug screens.	Agree. Naltrexone is primarily administered via injection. Why are urine drug screens or pill counts required? Even if using the pill form, what is the rationale for pill counts for a drug that has no abuse potential.

State Medical Board of Ohio

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SMBO Legislative Update: June 2024

Recent activity:

SB 109 – Sex Offenses (Sen. Hackett)

Regards sex offenses and individuals regulated by the State Medical Board

Of note:

- Increasing reporting requirements of suspected sexual activity by medical professionals; Allowing the board to suspend a license upon an indictment, as well as permitting an automatic 90 day suspension of a license of an individual whose license was suspended, revoked or surrendered in another jurisdiction; Requiring licensees to provide notification of their probationary status to their patients; Allowing the board to share the confidential investigation status of a licensee with the complainant; Adding a public member of the board to the internal investigatory process, to allow additional board insight into the handling of sexual misconduct

Status: Introduced 4/18/2023. Referred to Senate Judiciary Committee 4/19/2023. 1st Hearing Senate Judiciary 4/26/2023. 2nd Hearing Senate Judiciary 9/20/2023. 3rd Hearing Senate Judiciary 4/17/2024. REPORTED OUT of Senate Judiciary 4/24/2024. PASSED Senate Floor 4/24/2024. 1st Hearing House Criminal Justice 6/5/2024.

HB 73 – Prescriptions (Rep. J. Gross and Rep. M. Loychik)

To authorize the prescribing of off-label drugs

Of note:

- Allows a prescriber to issue a prescription for any drug, including an off-label drug, with informed consent of the patient
- Does not require the prescriber to obtain a test result, positive screen for a particular disease, or for the patient to have been exposed to an illness before issuing the prescription
- Does not allow a health-related licensing board to discipline a prescriber for any action taken under this bill

Status: Introduced 2/27/2023. Referred to House Health Provider Services Committee 2/28/2023. 1st Hearing Health Provider Services 3/28/2023. 2nd Hearing House Health Provider Services 4/25/2023. 3rd Hearing House Health Provider Services 5/2/2023. 4th Hearing House Health Provider Services 6/13/2023. REPORTED OUT of House Health Providers Services 6/20/2023. PASSED House Floor 6/21/2023. Referred to Senate Health Committee 9/13/2023. 1st Hearing Senate Health 5/8/2024. 2nd Hearing Senate Health 5/22/2024. 3rd Hearing Senate Health 6/12/2024

SB 56 – Interstate Massage Compact (Sen. Kristina Roegner)
To enter into the Interstate Massage Compact (Impact).

Of note:

- "Driver's License" Model: After verifying eligibility, the massage therapist is granted a multistate license which authorizes practice in all other compact member states. The massage therapist must maintain their "home state" license in good standing
- Member States must require continued competency as a condition of license renewal
- Applicant must have completed 625 hours clock hours of Massage Therapy education to qualify for a multistate license under the compact

Status: Introduced 2/14/2023. Referred to Senate Health Committee 2/22/2023. 1st Hearing Senate Health Committee 3/22/2023. 2nd Hearing Senate Health Committee 3/29/2023. 3rd Hearing Senate Health Committee 4/19/2023. 4th Hearing Senate Health Committee 5/24/2023. 5th Hearing Senate Health Committee 9/13/2023. REPORTED OUT Senate Health Committee 9/13/2023. PASSED Senate Floor 9/13/2023. Referred to House Commerce & Labor Committee 9/26/2023. 1st Hearing House Commerce & Labor Committee 10/10/2023. 2nd Hearing House Commerce & Labor Committee 10/24/2023. 3rd Hearing House Commerce & Labor Committee 11/14/2023. 4th Hearing House Commerce & Labor Committee 1/9/2024. REPORTED OUT House Commerce & Labor Committee 1/9/2024. PASSED House Floor 5/22/2024.

SB 28 – Physician Assistant (Sen. Kristina Roegner)
To enter into the Physician Assistant Licensure Compact

Of note:

- Allows participating states to grant compact privileges to a holder of a qualifying license
- Allows a participating state to charge a fee for granting compact privilege
- Licensee must be 2 years removed from any limitation or restriction on a license or compact privilege due to an adverse action
- Compact goes into effect after 7 states join

Status: Introduced 1/23/2023. Referred to Senate Health Committee 2/8/2023. 1st Hearing Senate Health Committee 3/1/2023. 2nd Hearing Senate Health Committee 3/8/2023. 3rd Hearing Senate Health Committee 3/15/2023. 4th Hearing Senate Health Committee 5/24/2023. 5th Hearing Senate Health Committee 6/14/2023. REPORTED OUT Senate Health Committee 6/14/2023. PASSED Senate Floor 6/21/2023. Referred to House Health Provider Services Committee 6/26/2023. 1st Hearing House Health Provider Services 4/9/2024. 2nd Hearing House Health Provider Services 4/16/2024. 3rd Hearing House Health Provider Services 5/14/2024. 4th Hearing House Health Provider Services 6/11/2024.

SB 211 – Dieticians (Sen. Kristina Roegner)
Enter the Dietitian Licensure Compact

Of Note:

- Enters Ohio as a party to the Dietician Licensure Compact, the purpose of which is to facilitate the interstate practice of dietetics and improve public access to dietetics services.

- Requires the State Medical Board to appoint a member to the Dietician Licensure Compact Commission within 60 days of Ohio entering the Compact.
- If a licensee's home state license is limited in any way, the licensee automatically loses the compact privilege in any remote state until the home state license is no longer limited.

Status: Introduced in the Senate 1/9/2024. 1st Hearing in Senate Health 4/10/2024. 2nd Hearing in Senate Health 4/24/2024. 3rd Hearing in Senate Health 5/8/2024.

Actively Monitoring

SB 81 – Health Professionals (Sen. Romanchuk)

To authorize certain clinical nurse specialists, certified nurse-midwives, and certified nurse practitioners to sign documents related to hospital patient admission, treatment, and discharge.

Of Note:

- Authorizes the following to sign documents related to patient admission, treatment, and discharge, if certain conditions are met: physician assistants, certified nurse practitioners, clinical nurse specialists, and certified nurse-midwives
- With respect to physician assistants, limits the bill's signature authority to hospital patients, while for certified nurse practitioners, clinical nurse specialists, and certified nurse-midwives, limits the bill's signature authority to psychiatric or behavioral health facility inpatients.

Status: Introduced in the Senate Health 3/7/2023. Referred to Senate Health Committee 3/8/2023. 1st Hearing Senate Health Committee (Substitute Bill accepts to include Pa's) 9/20/2023. 2nd Hearing Senate Health Committee 9/27/2023. 3rd Hearing Senate Health Committee 10/11/2023. 4th Hearing Senate Health Committee 11/15/2023. Reported out of Senate Health Committee 11/15/2023. PASSED Senate floor 29-1. Referred to House Health Provider Services 12/5/2023. 1st Hearing House Health Provider Services 12/5/2023. 2nd Hearing House Health Provider Services 2/6/2024. 3rd Hearing House Health Provider Services 4/9/2024. REPORTED OUT of House Health Provider Services 4/16/2024. PASSED House Floor 89-1. Senate CONCURRENCE 31-0.

SB 60 – Mental Health Assistants (Sen. Gavarone) (Companion HB 97)

To license certified mental health assistants

Of note:

- Defines "Certified Mental Health Assistant" as an individual who, under physician supervision, provides mental health care by engaging in any of the activities authorized in the bill
- Only practice under a supervision agreement with a supervising physician. Diagnose and provide treatment based on patient's diagnosis. Order, prescribe, personally furnish drugs. Refer patient for voluntary or involuntary admission for substance abuse disorder treatment or inpatient psychiatric care.

- CMHA may only prescribe the following controlled substances: Buprenorphine only for a patient actively engaged in opioid use disorder treatment. Benzodiazepine in the following circumstances – a patient diagnosed as having a chronic anxiety disorder or a patient with acute anxiety or agitation but only in an amount for 7 days. Stimulant approved by the FDA for treatment of ADHD
- SMBO rule making authority for: Standards and procedures for issuing and renewing licenses to practice, Application fees for initial license and renewed license, Application process, fees, requirements for approval, reapproval, and curriculum standards for education programs

Status: Introduced 2/16/2023. Referred to Senate Workforce & Higher Education Committee 2/22/2023. 1st Hearing in Senate Workforce & Higher Education Committee 3/1/2023. 2nd Hearing Senate Workforce & Higher Education 3/15/2023. 3rd Hearing Senate Workforce & Higher Education 5/31/2023. 4th Hearing Senate Workforce & Higher Education 10/3/2023. 5th Hearing Senate Workforce & Higher Education 10/31/2023. 6th Hearing Senate Workforce & Higher Education 11/15/2023. 7th Hearing Senate Workforce & Higher Education 5/21/2024

HB 97 – Mental Health Assistants (Rep. Pavliga) (Companion SB 60)

To license certified mental health assistants

Of note:

- Defines "Certified Mental Health Assistant" as an individual who, under physician supervision, provides mental health care by engaging in any of the activities authorized in the bill
- Only practice under a supervision agreement with a supervising physician. Diagnose and provide treatment based on patient's diagnosis. Order, prescribe, personally furnish drugs. Refer patient for voluntary or involuntary admission for substance abuse disorder treatment or inpatient psychiatric care.
- CMHA may only prescribe the following controlled substances: Buprenorphine only for a patient actively engaged in opioid use disorder treatment. Benzodiazepine in the following circumstances – a patient diagnosed as having a chronic anxiety disorder or a patient with acute anxiety or agitation but only in an amount for 7 days. Stimulant approved by the FDA for treatment of ADHD
- SMBO rule making authority for: Standards and procedures for issuing and renewing licenses to practice, Application fees for initial license and renewed license, Application process, fees, requirements for approval, reapproval, and curriculum standards for education programs

Status: Introduced 3/7/2023. Referred to House Health Provider Services 3/14/2023. 1st Hearing House Health Provider Services 5/23/2023. 2nd Hearing House Health Provider Services 6/20/2023. 3rd Hearing House Health Provider Services 11/14/2023.

HB 257 – Administrative Procedure (Rep. Jim Hoops & Rep. Thaddeus Claggett)

To authorize certain public bodies to meet, virtually

Of note:

- Will allow Medical Board advisory councils to meet virtually

Status: Introduced in House 8/22/2023. Referred to House Government Oversight Committee 9/12/2023. 1st Hearing House Government Oversight Committee 10/3/2023. 2nd Hearing House Government Oversight Committee 10/24/2023. 3rd Hearing House Government Oversight Committee 10/31/2023. 4th Hearing House Government Oversight 11/14/2023. Report out of House Government Oversight 11/14/2023. PASSED House floor 73-3. Referred to Senate Government Oversight 12/6/2023. 1st Hearing Senate Government Oversight Committee 2/28/2024

HB 89 - Health Examinations (Rep. B. Hillyer and Rep. M. Abdullahi)

Regards intimate examinations and anesthetized or unconscious patients

Of note:

- Prohibits an APRN, PA, physician or student from performing or authorizing another individual to perform, a pelvic, prostate or rectal examination on an anesthetized or unconscious patient.
- Exemptions include – The performance of the intimate examination is within the scope of care for the surgical procedure or diagnostic exam to be performed
- The patient or patients representation gives specific, informed consent for the intimate exam
- An intimate exam is required for diagnostic purposes or treatment of the patient's medical condition
- A court orders the intimate exam for the purpose of collecting evidence

Status: Introduced 3/7/2023. Referred to House Public Health Policy Committee 3/14/2023. 1st House Public Health Policy Hearing 4/19/2023. 2nd House Public Health Policy Hearing 5/3/2023.

HB 102 – Respiratory Therapists (Rep. T. Young and Rep. M. John)

To license advanced practice respiratory therapists and to amend the version of section 4761.01 of the Revised Code that is scheduled to take effect September 30,2024, to continue the change on and after that date

Of note:

- Allows for an APRT licensed under 4761.31 to exercise physician-delegated prescriptive authority. Prohibits a prescription for a controlled substance to be used outside of the healthcare facility the APRT is practicing
- Defines "Health Care Facility" as a hospital, A site where a medical practice is operated and provides direct patient care, an entity owned or controlled, in whole or in part, by a hospital or by an entity that owns or controls, in whole or in part, one or more hospitals, and any other facility designated in rule by the state medical board
- Requires supervising physician to be physically present at the location where the APRT is practicing or be readily available to the APRT through telecommunication in a location reasonably close to where the APRT is practicing

Status: Introduced 3/14/2023. Referred to House Health Provider Services Committee 3/22/2023. 1st Hearing House Health Provider Services 5/2/2023. 2nd Hearing House Health Provider Services 6/6/2023. 3rd Hearing House Health Provider Services Committee 6/11/2024.

HB 275 – OARRS (Rep. Plummer and Rep. T. Young)

To revise the law governing the review of patient information in the Ohio Automated Rx Reporting System, to establish requirements on the dispensing of opioid analgesics, to provide for a cash transfer.

Of Note:

- Requires health related licensing boards to adopt guidelines regarding patient counseling and education to be provided by a health care professional when prescribing an opioid analgesic for five or more days
- Revises the law requiring prescribers to review patient information in OARRS, by eliminating an exception for an opioid analgesic prescribed or personally furnished for seven days

Status: Introduced in the House 9/18/2023. Referred to House Health Provider Services Committee 9/26/2023.

SB 278 – Medical and Recreational Marijuana (Sen. S. Huffman and Sen. K. Schuring)

Modify regulation of medical marijuana, adult use cannabis, hemp

Of Note:

- Adds to list of qualifying medical conditions for medical marijuana the following: arthritis, migraines, autism spectrum disorder, spasticity or chronic muscle spasm, hospice care or terminal illness, opioid use disorder; and any condition not specified in this division that a recommending physician is qualified to treat and considers.
- No changes to the code section which lays out the petition process for Medical Board review of requests for a disease or condition to be added as a qualifying medical condition.

Status: Introduced in the Senate 5/28/2024.

Closely Monitoring

HB 80 – Pharmacist Care (Rep. S. Lipps)
Regards pharmacist care

Of note:

- Allows a pharmacist to conduct screenings and order lab tests and diagnostic tests and evaluate the results of the screenings, in order to treat: Influenza, COVID-19 and Group A streptococcus
- Allows a pharmacist to initiate drug therapy when treating one of the above health conditions

Status: Introduced 2/27/2023. Referred House Health Provider Services Committee 2/28/2023.

HB 169 – Sun Lamp Tanning (Rep. B. Hillyer)
To prohibit the provision of sun lamp tanning services to individuals under age 18 and to make changes regarding the titles that may be used by physicians

Of note:

- Includes “Doctor of Medicine”, “Doctor of Osteopathy”, “surgeon”, and “dermatologist” to the titles that may be used by physicians.

Status: Introduced 5/9/2023. Referred to House Health Provider Services Committee 5/23/2023. 1st Hearing House Health Provider Services 6/6/2023. 2nd Hearing House Health Provider Services 6/27/2023. 3rd Hearing House Health Provider Services 9/27/2023. 4th Hearing House Health Provider Services 10/10/2023. 5th Hearing House Health Provider Services 12/5/2023.

HB 255 – Massages (Rep. Kevin Miller & Rep. Haraz Ghanbari)
To make changes to the laws governing massage establishments and to establish a nontherapeutic massage registration.

Of note:

- Creates the nontherapeutic massage registration under the Department of Public Safety

Status: Introduced in House 8/16/2023. Referred to House Criminal Justice Committee 9/12/2023.

SB 9- Medical Marijuana (Sen. S. Huffman & Sen. Kirk Schuring)
To amend the law related to medical marijuana

Of Note:

- Creates the Division of Marijuana Control with the Department of Commerce for the purpose of overseeing Ohio's Medical Marijuana Program
- Expands the qualifying medical conditions to include – Arthritis, Migraines, Autism spectrum disorder, Spasticity or chronic muscle spasms, Hospice care or terminal illness, Opioid use disorder and any condition not specified that a recommending physician is qualified to treat and considers as debilitating to the patient as the conditions listed
- Allows the medical director of a dispensary to hold a CTR
- Allows SMBO to approve a course of education for employees of a medical marijuana dispensary

Status: Introduced 1/11/2023. 1st Hearing Senate General Government 1/17/2023. 2nd Hearing Senate General Government 2/7/2023. 3rd Hearing Senate General Government 3/7/2023. 4th Hearing Senate General Government 3/14/2023. 5th Hearing Senate General Government 4/18/2023. 6th Hearing Senate General Government 5/10/2023. 7th Hearing Senate General Government 5/16/2023.

Operationalizing

HB 33 – Operating Budget (Rep. Jay Edwards)

To make operating appropriations for the biennium beginning July 1,2023, and ending June 30, 2025, to levy taxes, and to provide authorization and conditions for operation of state programs.

Of note:

- **Intravenous administration of ultrasound enhancing agents – sonographers**
  - Allows a sonographer to administer intravenously ultrasound enhancing agents if the sonographer meets certain requirements.
- **Legacy pain management study committee**
  - Establishes the Legacy Pain Management Study Committee to study and evaluate the care and treatment of patients suffering from chronic pain, in particular those who have been prescribed opioids for lengthy periods of time. The committee is to be made up of 4 members of the General Assembly, one representative of OMHAS, one representative of SMBO, one representative of PRX, one member representing patients, and one member representing prescribers.
  - Requires the committee to consider availability of and access to pain management specialists in Ohio and the challenges associated with tapering opioid doses.
  - Requires the committee to prepare and submit a report of the recommendations for legislation to address the care and treatment of legacy patients to the General Assembly by December 1, 2024.
- **Practice of acupuncture and herbal therapy**
  - Authorizes a licensed acupuncturist with a national certification in Chinese herbology or oriental medicine to practice herbal therapy; Eliminates supervisory requirements for newly licensed acupuncturists, including duties and

reimbursement allowances for supervising physicians and chiropractors. This language is in regards to 2021 removal of the oriental medicine practitioners.

- **Practitioner impairment monitoring**
- Revises the law governing SMBO's confidential program for treating and monitoring impaired practitioners in the following ways:
    - Renames the program as the Confidential Monitoring Program, instead of One-Bite
    - Extends the program's treatment and monitoring services to practitioners who are or may be impaired and practitioners unable to practice because of mental or physician illness and specifies that impairment includes substance use disorder
    - Requires SMBO to notify the monitoring organization that is under contract to conduct the program of practitioner's potential impairment
    - Transfers to the monitoring organization SMBO's the authority to approve treatment providers
    - Requires the monitoring organization, as a condition of eligibility to conduct the program, to be a professional health program
    - Requires the program to employ any licensed health care practitioners necessary for its operation, in place of the One-Bite Program's requirements to employ specified types of practitioners
    - Modifies a condition of practitioner eligibility related to prior professional discipline, by instead prohibiting a practitioner from participating if still under terms of a consent agreement or SMBO order
    - Eliminates the requirement that a practitioner suspend practice while participating in the program, instead requiring suspension only if the monitoring organization, evaluator, or treatment provider recommends it
    - Authorizes SMBO to contract with the monitoring organization to assist SMBO in monitoring practitioners subject to formal disciplinary action.
- **Medical Board license holders-retired status**
    - Establishes a process by which practitioners licensed by SMBO may have their licenses placed on retired status. Requires SMBO to place a license on retired status if certain eligibility conditions are met. Prohibits the holder of a license placed on retired status from practicing under the license, but does allow the holder to continue to use any title authorized for the license. This language allows for a path of dignified retirement for a physician. The language also have built in safeguards to reactivate the license if the physician complies with the fitness to practice requirements in current law.
- **Criminal background checks under Interstate Medical Licensure Compact**
    - Clarifies that applicants under the existing Interstate Medical Licensure Compact are required to comply with Ohio's existing procedure for criminal records checks for licensees.
- **Subpoenas for patient record information**
    - Eliminates requirements that the supervising member of SMBO approve the issuance of subpoenas for patient record information and be involved in probable cause determinations related to such subpoenas, making the secretary of SMBO solely responsible for those requirements.
- **Time limit to issue adjudicative order**

    - Increases the time SMBO has to issue a final adjudicative order related to the summary suspension of a physician assistant's license to 75 days (from 60). This amendment will bring it into line with analogous language that concerns other license types.
- **Public address information for SMBO licensees**
    - Clarifies the public facing directory of licensees published by the medical board containing only the name and business address of the licensee. Also, specifies the address on file with the state medical board during a medical malpractice claim is the business address.
- **Prescribing for outpatient behavioral health – physician assistants**
    - Authorizes a physician assistant to prescribe schedule II controlled substances if the prescription is issued at the site of a behavioral health practice that does not otherwise qualify under current law as a site where physician assistants may prescribe those drugs. An earlier version of the budget included this language for APRN's, this is to align PA's with the APRN's.
- **Administrative Procedure Act adjudications**
- Does the following regarding agencies conducting an adjudication under the Administrative Procedure Act (APA), unless another law applies:
    - (1) Authorizes additional document service methods through email, facsimile, or domestic commercial delivery service, and
    - (2) allows for alternative methods to complete service if initial attempts fail, including using alternative addresses, before publishing notice in a newspaper of general circulation.
    - Increases, from 15 to 60, the maximum number of days within which an agency generally must hold an administrative hearing after a party to an adjudication requests one.
    - Requires certain notices and orders that must be served on a party in an APA adjudication to be provided to the party's attorney or other representative rather than requiring the notices be mailed as under current law.
    - Specifies that an agency's rejection of an application for registration or renewal of a license is not effective until the 15th day after notice of the rejection is mailed to the licensee instead of prohibiting such an action from becoming effective 15 days before the notification mailing date as under current law

Status: Introduced 2/15/2023. PASSED House Floor 4/26/2023. Referred to Senate Finance Committee 5/3/2023. PASSED Senate Floor 6/15/2023. House refuses to Concur in Senate Amendments 6/21/2023. House and Senate Adopt Conference Report 6/30/2023. Signed by the Governor 7/3/2023. Effective Date: 10/1/2023.

SB 21 – Court Jurisdictions (Sen. Rob McColley & Sen. Michelle Reynolds)

To generally change the venue in which appeal from an agency order is proper to the local court of common pleas.

Of note:

- Requires an appeal from an order issued by an administrative agency be made to the Franklin County Court of Common Pleas or the court of common pleas in the county in

which the place of business of the licensee is located or the county in which the licensee is a resident
- Requires appeals from an administrative order by any party who is not a resident of Ohio must be to the Franklin County Court of Common Pleas.

Status: Introduced 1/11/2023. 1st Hearing Senate Judiciary 1/17/2023. 2nd Hearing Senate Judiciary 2/7/2023. 3rd Hearing Senate Judiciary 2/8/2023. 4th Hearing Senate Judiciary 2/15/2023. REPORTED OUT Senate Judiciary 2/15/2023. PASSED Senate Floor 2/22/2023 24-7. Referred in House Civil Justice Committee 2/28/2023. 1st Hearing House Civil Justice 3/7/2023. 2nd Hearing House Civil Justice 3/14/2023. 3rd Hearing House Civil Justice 3/21/2023. 4th Hearing House Civil Justice 5/16/2023. 5th Hearing House Civil Justice 5/23/2023. Passed House Civil Justice 5/23/2023 9-5. PASSED House Floor 6/14/2023 67-26. Senate Concurs in House Amendments 6/15/2023 24-7. Signed by the Governor 6/30/2023. Effective 9/28/2023.

SB 131 – Occupational Licensing (Reciprocity) (Sen. Roegner and Sen. McColley)

To require an occupational licensing authority to issue a license or government certification to an applicant who holds a license, government certification, or private certification or has satisfactory work experience in another state under certain circumstances.

Of note:
- Requires automatic licensure of out of state applicants that meet certain criteria.
- Allows for the licensing authority to take disciplinary action against an applicant, deny an application and determine fitness to practice of an applicant.
- Amended – A person who holds a license issued through an interstate licensure compact to which Ohio is a party is not required to obtain a license through reciprocity
- Amended – Delays the bill's effective date to 270 days after the bill's effective date

Status: Introduced in the Senate 3/16/2021. 1st Senate Workforce & Higher Education hearing 5/19/2021. 2nd Senate Workforce & Higher Education hearing 5/26/2021. 3rd Senate Workforce & Higher Education hearing 3/22/2022. 4th Senate Workforce & Higher Education hearing 5/18/2022. 5th Senate Workforce & Higher Education hearing 5/25/2022. Reported out of Senate Workforce & Higher Education 5/25/2022. Passed the Senate 6/1/2022. Referred to House State & Local Government Committee. 1st House State & Local Government Committee Hearing 11/30/2022. 2nd House State & Local Government Committee Hearing 12/13/2022. Passed House State & Local Government Committee 12/14/2022. Passed House 12/14/2022. Senate Concurs in House Amendments 12/14/2022. Signed by Governor 1/2/2023.

HB 509 – Revise and streamline occupational regulations (Rep. John and Rep. Fowler Arthur)

Of Note:
- Amended to include language changing massage therapy curriculum from 600 hours of specified course hours to 600 hours of instruction in massage therapy

Status: Passed out of the House 3/23/2022. Referred to Senate Workforce & Higher Education 3/29/2022. 1st Senate Workforce & Higher Education hearing 5/25/2022. 2nd Senate Workforce

& Higher Education hearing 11/16/2022. 3rd Senate Workforce & Higher Education hearing 11/30/2022. 4th Senate Workforce & Higher Education hearing 12/7/2022. Passed Senate Workforce & Higher Education 12/7/2022. Passed Senate Floor 12/7/2022 29-0. House Concurs in Senate Amendments 12/14/2022. Signed by Governor 1/5/2023.